

**DEPARTMENTS OF LABOR, HEALTH AND  
HUMAN SERVICES, AND EDUCATION, AND  
RELATED AGENCIES APPROPRIATIONS FOR  
FISCAL YEAR 2008**

---

**TUESDAY, APRIL 17, 2007**

U.S. SENATE,  
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,  
*Washington, DC.*

The subcommittee met at 2:05 p.m., in room SD-124, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.  
Present: Senators Harkin, Durbin, Reed, and Specter.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**CENTERS FOR DISEASE CONTROL AND PREVENTION**

**STATEMENT OF DR. JULIE GERBERDING, DIRECTOR**

**OPENING STATEMENT OF SENATOR TOM HARKIN**

Senator HARKIN. Good afternoon, the Subcommittee on Labor, Health, Human Services, Education, and Related Agencies of the Appropriations Committee will come to order.

The subcommittee has invited a number of distinguished witnesses to appear before this hearing and this subcommittee, to tell us more about a very important issue, autism.

The Centers for Disease Control and Prevention estimates that 1 of every 157 children born this year will be diagnosed with autism. Millions of families across the country are facing the very real difficulties in coping with this disease.

It's tough on parents who would do anything to help their children at home, while at the same time, fighting to find the supportive services that their children so badly need. We hear the heartbreaking stories, day after day, about families just trying to get the best treatments for the children, and wondering why it's their family that faces this ordeal.

I know we have heard from several families and groups, and I want to thank them for sharing their stories.

This hearing will address a number of questions. First, is the prevalence of autism on the rise, both in the United States and other countries? If so, why is that? Is there really an increase in children of autism, or is the disease being better diagnosed? I keep hearing both sides of that debate.

Second, of course, what causes autism? Is it environmental, is it genetic? Is it a combination of both? Imagine my surprise, when I

read the last issue of Discover magazine. It had a big story in there about understanding autism, and the subtitle is, The Answer May Lie in the Gut, Not in the Head, saying that there may be a direct link between physical illness—physical illness—and the onset of autism. So, again, I’ll be asking questions about that article. [Discover magazine, April 2007, “Autism: Its Not Just in the Head,” by Jill Neimark.]

Third, what therapies work best for children with autism? Are parents able to find the services they need for their kids, and at what cost?

As Dr. Favell will point out, and also Marguerite Colston in her testimony, that in looking for a cure and putting more research dollars out there, and trying to find how we have a cure, or a good intervention, we can’t forget the families need help now. Now—not 10 years from now, they need help right now—in finding the best possible support for their children.

So, we have two panels of witnesses today. The first panel will be, of course, Dr. Julie Gerberding, the Director of the Centers for Disease Control and Prevention, who will talk about the incidents, and prevalence, of autism. Dr. Thomas Insel, the Director of the National Institute of Mental Health, will bring us up to date on some of the science.

#### PREPARED STATEMENT

Our second panel will include Dr. Judy Favell, who has done great work with young children with autism; Marguerite Colston, a parent of a child with autism who can speak to the issue from the perspective of a parent; Mr. Bob Wright, the Co-Founder of Autism Speaks; and, Bradley Whitford, actor; as well as, former Deputy Chief of Staff to President Jed Bartlett (on TV, of course) and foremost an advocate for children with autism.

[The statement follows:]

#### PREPARED STATEMENT OF SENATOR TOM HARKIN

Good Afternoon. The subcommittee has invited a number of distinguished witnesses, this afternoon, to bring us up to date on a very important topic: the status of autism, and of autism research, in the United States. The Centers for Disease Control and Prevention estimates that one of every 157 children born in the United States this year will be diagnosed with autism. Millions of families are grappling with the profound difficulties of understanding and coping with this disease. My heart goes out, in particular, to parents who go to heroic lengths to assist their autistic children at home, and who fight the daily fight to secure the support services that their children so badly need.

This hearing will look at several key questions:

First, the number of diagnosed cases of autism is on rise, both in the U.S. and in other countries. Why is this? Are we simply doing a better job of diagnosing autism, or has there been a real increase in the incidence of this disease?

Second, what causes autism? Are the causes environmental? Are they genetic? My guess is that it is a combination of the two, but I am eager to hear the views of our witnesses.

Third, which therapies work best for children with autism? And are parents able to find the services they need for their children, and at what cost? As Dr. Favell points out in her testimony: while doing research on causes and cures is important, people need help now to overcome or lessen the effects of autism.

Last, what is the outlook for finding a cure for autism? And what more can the federal government do to help?

We will have two panels of witnesses today. The first panel includes Dr. Julie Gerberding, the Director of the Centers for Disease Control and Prevention, who will talk about the incidence of autism; and Dr. Thomas Insel, Director of the Na-

tional Institute of Mental Health, who will bring us up-to-date on the science and research.

Our second panel includes Dr. Judy Favell, who has done great work with young children with autism; Marquerite Colston, a parent of a child with autism, who will speak to this issue from the perspective of a parent; Bob Wright, the co-founder of Autism Speaks; and Bradley Whitford, former deputy chief of staff to President Jed Bartlett—actually, a very accomplished actor—and an outspoken advocate for children with autism.

Senator HARKIN. With that, I will turn to my colleague, Senator Specter.

#### OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you, Senator Harkin, for convening this very important hearing on this very debilitating disorder. We have seen a significant increase in the funding by the National Institute of Health for autism research from \$27 million in 1998, to the current funding of \$108 million. CDC funding for autism has grown from \$281,000 in 1998, to \$15.1 million today.

My view is that the funding through the NIH is insufficient. As is generally known, Senator Harkin and I have taken the lead on increasing the funding for the National Institutes of Health from \$12 billion to \$29 billion. During the course of the past decade, we have re-allocated priorities within this subcommittee—as we frequently say, the gavel has changed seamlessly between the two of us over the course of the past decade and a half—and in some years, have increased NIH's funding by as much as \$3.5 billion.

This year, with a lot of pressure, the budget resolution came forward with an additional \$1.5 billion, and Senator Harkin and I added an amendment to add \$2.2 billion more to the National Institutes for Health.

Candidly, a budget resolution is only Confederate money, it doesn't really count until there is an allocation. Senator Harkin and I are working our way up the seniority route, and we're getting to be closer to the coveted status of chairman of the Appropriations Committee. Only Senator Cochran is ahead of me on the Republican side, and it's a great position to have to be able to deal in real dollars when those allocations are made.

But, we hear parents across the country tell us about their children with autism, and it's an ailment, a malady, which I think could be, could be solved if we had sufficient research intensity.

For a moment, on a purely personal note, one of the leading national advocates on this subject is John Shestack, who is the son of a very prominent lawyer, Jerome Shestack in Philadelphia—longstanding friend of mine—and, his mother Marcia Rose is a noted television personality. John and his wife, Portia, have established a foundation, one of the largest non-governmental funding resources for autism, and they have recently joined with Bob and Suzanne Wright for the February merger of their two leading autism organizations.

So, it is very heartening to see this in the private sector, and Senator Harkin and I, and this committee—and I think, really, the whole Congress—are determined to increase funding so we can find an answer to autism.

Regrettably, I'm not going to be able to stay for the entire hearing today, we are very deeply involved in the issue with the De-

partment of Justice and the resignation of the U.S. Attorneys which is taking a great deal of time, and I'm going to have to excuse myself partway through this hearing to attend there, but I will stay for as long as I can.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much, Senator Specter. Again, thank you for our close working relationship over all these years, and for your continued commitment to bio-medical research and especially to this very important issue of autism.

I had dinner Sunday night with a couple whose child is autistic, and all I can say is that we've got to get the families some help. People are looking to us for answers and some help. Hopefully this hearing today will point us in the right direction.

So, let's get started, and I'll just make it clear that all of your statements will be made part of the record in their entirety. I'm going to ask each of our witnesses to try to sum it up in about 5 minutes. But if you get around 7 minutes or so, I might start motioning for you to quit.

So, if you could just sum it up for us, and then I'm going to ask both you, Dr. Gerberding and Dr. Insel, at the end of your presentations, to maybe take a seat on either end, and we'll bring up the other witnesses. It's not my intent to question you at that time—but to question everyone all at once.

Okay? So, we'll kick it off first with Dr. Julie Gerberding, the Director of the Centers for Disease Control and Prevention. Dr. Gerberding, welcome back.

#### SUMMARY STATEMENT OF DR. JULIE L. GERBERDING

Dr. GERBERDING. Thank you, it's good to be back. We really appreciate the committee's interest in this topic. Is my microphone on, can you hear me okay?

Senator HARKIN. Yes.

Dr. GERBERDING. We are very grateful for all of the support that the committee has given us, and particularly for our ability to expand our autism activities significantly.

Senator Harkin, I also know that you walk your talk on this issue, having had a chance to be with you at the summer Olympics—the Special Olympics last summer—and knowing your commitment to developmental disabilities, and disabilities of all nature. So we really appreciate your championing this issue.

I'd like to share with you the CDC perspective on autism and the work that we're doing. It's important to appreciate that we recognize that we're talking about a spectrum of diseases here, not a single disease. We're talking about autism, per se, about pervasive developmental disorders, and some other conditions that have characteristics in common with autism—Asperger's disorder and some other conditions—and these are diseases that are not diagnosed by a test. They're diseases that are diagnosed by observing behaviors, and watching behaviors change and develop over time. So, there's a lot of difficulty in making a distinction between who has what, and where one of these conditions leaves off and the other one begins.

We know that autism has a tremendous impact on children who are affected as well as their families and the people who care for

them. The diseases are characterized primarily by difficulties in forming relationships, and engaging in the kind of social interactions and communications that enrich life, and allow people to effectively communicate with one another.

Many of these children also have differences in the way they respond to stimuli in the environment; the way they learn, the way they play, and the way they experience their life overall.

The bottom line is, there is no cure for autism now, and these effects can last a lifetime. We also know that the sooner we make the diagnosis of autism spectrum disorders, the more likely children are to benefit from interventions, and so it's imperative that we not wait until the full-blown syndrome has evolved, but that we have early detection and characterization.

Under the Combating Autism Act, CDC has three main responsibilities. One is, to answer your first question, what is the prevalence of autism in our communities, and is it changing over time, and who is at risk, why and when?

Our second priority is research. We are engaged in several kinds of epidemiologic research that will help us look at a variety of the hypotheses about causality, and try to make some determinations about which are the most promising associations, and what can we learn about cause that could help us lead to intervention, or even treatment.

Last, and importantly, is our responsibility for awareness. We need to be able to inform parents and caregivers, as well as teachers and clinicians about the full spectrum of these conditions so that earlier diagnosis is possible. We also need to improve community awareness so that children can live more comfortably in their communities, and overall public awareness so that we have the kind of support we need to solve these problems.

Just recently, CDC published information about the rate of autism in communities around our country. I'm going to focus on the communities that were reporting data in 2002, we also have a report from 2000, and there will be an upcoming report on information from 2004. But the information from 2002, probably is the largest sample, and so I'm going to focus on that—this represents about 10 percent of 8-year-old children in our country, so it's not everyone, it's not every community, but it's a significant proportion.

What was found in this study is that about 1 in 150 children have autism. Boys, in general, were more likely than girls, and at least some of the sites showed that white children were more likely to have autism than non-white children. So, this is a healthy—a helpful—perspective, but we can't yet say anything about trends over time, until these studies go on for a longer period of time.

We also have initiated a set of studies in a group of sites called CADRE, Centers for Autism and Development Disabilities Research and Epidemiology. And this is a study that will allow us to look at causes. We're going to compare children who have these disorders, with children who have other disabilities, and children who are normal, and look for the frequency of a variety of factors, including infections, as you mentioned in the *Discover* magazine, their parents' health status, their family health status, their genes and so on and so forth. We will be able to tease out of that leading hypothesis about why are children with autism different from chil-

dren who have other conditions, or who don't have a developmental disability. This is a project we're starting this spring, and we will probably have information from the study over the next couple of years.

The last point I wanted to make very quickly, was the importance of awareness. We know that at least half of children with autism have obvious symptoms and signs before they're age three, but most children with autism are not diagnosed until they are 4 or 5 years old, so there's a gap between when it should be completely clear what is going on, and the gap when they come to attention.

So, we initiated this "Learn the Signs, Act Early" campaign to target parents, health professionals and caregivers in pre-school and daycare to be able to recognize the child who is at risk, or who may have early signs. Of course, we're doing this with a number of our partners.

This has been an incredibly effective campaign already. Pediatricians now indicate that they have the tools to be able to diagnose autism at least two-thirds of the time, parents understand that this disease can be detected through developmental screening, and an increasing proportion of doctors recognize that you can diagnose autism as early as 18 months, and that you need to initiate the screening much earlier than when the child enters school, which is often when these conditions are initially detected.

#### PREPARED STATEMENT

So, we're going to continue this awareness campaign, we hope that will create a platform so that the work that we're doing on research, on causality and interventions will have a better chance to really make a difference.

So, I—again, I thank you for your attention, and I look forward to being able to answer some specific questions that you mentioned at the beginning of this hearing.

[The statement follows:]

#### PREPARED STATEMENT OF DR. JULIE L. GERBERDING

Good afternoon, Senator Harkin and distinguished members of the subcommittee. Thank you for the opportunity to appear before you on behalf of the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services, to discuss our agency's research and prevention activities addressing autism spectrum disorders. Thank you also for your continued support of CDC's goals in support of healthy people throughout all stages of their lives and facets of living. Good health is essential to a good life, and the health and well-being of a Nation's people are essential for its continued strength and growth.

Today, our Nation and the world are focused on urgent threats such as pandemic influenza, natural disasters, and terrorism. While these threats require and deserve our immediate attention, we cannot lose sight of the pressing realities of public health issues that we face every day, such as autism and other developmental disabilities. Autism spectrum disorders include autistic disorder, pervasive developmental disorder—not otherwise specified (PDD-NOS, including atypical autism), and Asperger's syndrome.

Autism spectrum disorders cause considerable impairments in social interaction and communication that show up early in a child's life—before the family celebrates the child's third birthday—and can dramatically affect a child's ability to participate in activities with loved ones, caregivers, and peers. It is often difficult for a child with an autism spectrum disorder to communicate and interact with others, and they can retreat from group activities. An affected child may also have unusual ways of learning, paying attention, or reacting to different sensations, and can show unusual behaviors and interests. There's no cure at this time, and the effects of these disorders can last a lifetime. The profound lifelong impact of autism spectrum

disorders, tremendous costs to the affected individuals and their families, the lack of known causes or cures, and concerns about the increased rates of diagnosis all make autism spectrum disorders one of our urgent realities, and a top concern for many families, health professionals, educators, and local and national organizations.

CDC's efforts on autism spectrum disorders are led largely by our National Center on Birth Defects and Developmental Disabilities (NCBDDD), which was created following the Children's Health Act of 2000. The Center takes a life-span approach by working to identify and prevent birth defects and developmental disabilities—including autism spectrum disorders—and by promoting the health of children and adults with disabling or potentially disabling conditions. The Center's top priorities are improving health and wellness for people with disabilities, preventing birth defects, and addressing autism and related conditions.

As reauthorized by the Combating Autism Act of 2006 (Public Law 109-416), NCBDDD's work in autism spectrum disorders focuses on three broad areas—understanding rates and trends, advancing public health research in the search for causes or a possible cure, and improving early detection and diagnosis so that affected children can begin receiving intervention as soon as possible. Early intervention that provides structure, direction, and organization can often help a child with an autism spectrum disorder. Today, I will provide an update on the prevalence of autism spectrum disorders, discuss the launch of CDC's epidemiologic study of potential causes and correlates, and share with you some of our successes in promoting early identification of autism spectrum disorders and other developmental disabilities.

#### CDC'S WORK IN AUTISM SPECTRUM DISORDERS PREVALENCE

Parents, policy makers, and the public want to better understand how many people are affected by autism spectrum disorders—and whether the higher rates are due to better identification or a true increase in the occurrence. In order to address these questions about rates and trends, we have focused our efforts on developing prevalence estimates of autism spectrum disorders in multiple communities over time. "Prevalence" is the number of existing disease cases in a defined group of people during a specific time period, and it should be differentiated from "incidence," which is the number of new cases for a given period of time.

Previous efforts to understand the prevalence of these conditions have varied widely in their methods and findings—making it difficult to accurately answer critical questions about trends. For example, studies published before 1985 indicated that the prevalence of autism and related conditions was 0.4–0.5 per 1,000 children. However, later studies using updated diagnostic criteria and differing methods from multiple countries have identified rates ranging from 2.0 to 12.0 per 1,000 children with "best estimate" rates ranging from 2.0 to 6.0 per 1,000 children. Two previous CDC studies specific to U.S. communities from the mid-1990s found rates of 3.4 and 6.7 per 1,000 children 3–10 years of age and have identified the urgent need for population-based autism spectrum disorder prevalence monitoring in the United States.

CDC has been monitoring the prevalence of developmental disabilities since the 1980s and autism spectrum disorders specifically since 1996. Since 1999, CDC and its partners in 14 States have been building the Autism and Developmental Disabilities Monitoring (ADDM) Network to better understand the size and characteristics of the population of children with autism spectrum disorders, and to provide consistent and reliable estimates over time. This network, the only one of its kind, provides multiple-site, multiple-source, population-based prevalence data on the number of children with an autism spectrum disorder. CDC began with six sites (Arizona, Georgia, Maryland, New Jersey, South Carolina, and West Virginia) in 2000 and in 2002 expanded to include eight additional sites (Alabama, Arkansas, Colorado, Missouri, North Carolina, Pennsylvania, Utah, and Wisconsin). Today, we are continuing our surveillance efforts in 10 of these sites. While this method does not provide a nationally representative sample, the network represents the largest effort to monitor prevalence to date, capturing up to 10 percent of the U.S. population of 8-year-old children. The network aims to provide accurate information and a strong basis for bringing autism and developmental disabilities surveillance to scale, similar to our national efforts in monitoring other urgent realities.

#### RECENT PREVALENCE ESTIMATES

Together with our partners in the ADDM network, CDC is beginning to answer one of the critical concerns that I discussed earlier—are rates of autism spectrum disorders truly increasing? In February of this year, the CDC released the largest summary of prevalence data from multiple U.S. communities ever reported. The results showed an average of 6.7 children out of 1,000 with an autism spectrum dis-

order in the six communities assessed in 2000, and an average of 6.6 children out of 1,000 with an autism spectrum disorder in the 14 communities included in the 2002 study. The average finding of 6.6 and 6.7 per 1,000 eight-year-olds translates to approximately 1 in 150 children in these communities. This estimate is consistent with the upper end of prevalence estimates from previously published studies, with some of the communities having an estimate higher than those previously reported in U.S. studies. Reported rates ranged from about 1 in 100 to 1 in 300 children in the 2002 study year.

Six of the participating sites (Arizona, Georgia, Maryland, New Jersey, South Carolina, and West Virginia) reported data in both 2000 and 2002. Autism spectrum disorder prevalence was similar across the 2 years in four of the six sites. New Jersey's prevalence estimates are higher than all other sites in both years, but did not increase significantly between 2000 and 2002. In West Virginia, the prevalence estimate is significantly higher in 2002 than in 2000; the prevalence in Georgia appears to have increased, but not significantly. While the stability of autism spectrum disorders in four of the six sites is fairly consistent, the increase in two sites is a concern.

As anticipated, the findings from both study years confirmed a higher prevalence for boys than girls; this finding is consistent with past studies. Also, the data show some differences in rates among children by race or ethnicity. Similar to past reports, prevalence rates in most sites were similar for white and black children; however, five of the 14 sites found a higher prevalence among white children compared to estimates for black children.

In addition to measuring prevalence and demographic differences, the studies looked at when parents and others first noted signs of developmental concerns in their children. We know that autism and related conditions can be diagnosed as early as 18 months. However, these studies showed that up to 88 percent of children with an autism spectrum disorder had documented developmental concerns before the age of three, but half of these were diagnosed between 4½ and 5½ years. It is of critical importance to diagnose the child as early as possible, as early intervention services hold the most promise to improve the quality of life for these children and their families.

The 2000 and 2002 data points do not constitute a trend, but they do provide important baseline information on the prevalence of autism spectrum disorders in multiple areas of the United States. As I mentioned earlier, we are continuing to work with our network partners on prevalence estimates for 10 of these same sites for 2004 and 2006. Since the system has now been established, I expect information for these new data points will come more quickly, hopefully by the end of 2008.

I want to stress that CDC and many of our public and private partners see these numbers as an important step in understanding autism spectrum disorders, but more importantly, we recognize that "1 in 150 children" represents the lives of the hundreds of thousands of children and parents touched by autism and related conditions. Because of this, we are committed to the search for answers. We are also working to ensure that parents, health care and child care professionals, and everyone who cares for children, are able to recognize the early signs of autism spectrum disorders. In the absence of a cure, early identification and action hold the most promise for affected children and families.

#### EPIDEMIOLOGIC RESEARCH

We all want to know the causes of autism and related conditions. In addition to building a public health surveillance network for developmental disabilities, CDC has also been researching potential causes. Following the passage of the Children's Health Act of 2000, CDC has been working closely with partners in five sites to develop the Centers for Autism and Developmental Disabilities Research and Epidemiology, or CADDRE. This multi-state collaborative study will help to identify factors that may put children at risk for autism spectrum disorders and other developmental disabilities.

CADDRE is a collaborative effort from which we expect to build a large pooled data set that will be used to examine priority research questions. As the largest epidemiologic study of its kind, it holds the potential to be an important complement to the array of other work occurring at the National Institutes of Health and in academia. It is important to note that what CDC brings to autism spectrum disorder research is a unique perspective of studying health issues in large populations—not just among individuals or families who self-refer for intervention or study. To date, CADDRE sites have studied conditions that often occur with autism spectrum disorders, screening and management, and associations with immune system and genetic and environmental factors.



Later this spring, CADDRE will begin data collection to study a number of factors for their potential association with autism spectrum disorders. Known as the Study to Explore Early Development (SEED), the factors include: infections or abnormal responses to infections in the child, mother, or father; genetic factors in the child, mother and father; mother's reproductive history; abnormal hormone function in the child, mother or father; gastrointestinal problems in the child; family history of medical and developmental problems; select environmental exposures; behaviors during pregnancy; and parents' occupations and other socio-demographic factors. The information will be obtained by conducting interviews and exams, reviewing medical records, and by collecting cheek swabs and blood and hair samples.

Several steps in the development of SEED have already been completed. The protocol has been written, and Institutional Review Board approval has been obtained. In addition, site-specific advisory boards have been established to review the study materials and the study design. Focus groups with parents of children—with and without developmental disabilities—were conducted to obtain additional feedback on the study design and feasibility of the study. The implementation and quality control protocols for all aspects of SEED field work have been developed and “train-the-trainer” sessions for field implementation procedures have been completed. Data sharing protocols and general analysis plans have been developed, and the CADDRE Information System (web-based subject tracking and data collection application) has been established. We expect data collection to take 3 to 4 years, and preliminary results would be available shortly thereafter.

Study participants will include approximately 3,000 children ages 2–5 years and their parents. All study children will be drawn from the cohort of children born and currently residing in the study areas of each CADDRE site in select birth years. Three groups of children will be selected: children identified with autism spectrum disorders, children identified with other developmental problems, and a random sample of all children in each area born in the selected birth years (most of them typically developing).

#### LEARN THE SIGNS. ACT EARLY.

Recent studies have shown that developmental disabilities such as autism spectrum disorders can be diagnosed as early as 18 months; however, we know that about half of all children are not diagnosed until much later. Early intervention is a child's best hope for learning to communicate and connect with his or her parents and friends and to be able to learn in a classroom with his or her peers.

CDC, in collaboration with a number of national partners—the American Academy of Pediatrics (AAP), Autism Speaks (Cure Autism Now and the National Alliance for Autism Research, which have both recently merged with Autism Speaks), the Autism Society of America (ASA), First Signs, the Interagency Autism Coordinating Committee (IACC), and the Organization for Autism Research (OAR)—launched a national public awareness campaign in 2004 called Learn the Signs. Act Early. The campaign aims to educate parents, health care professionals, and child care providers about child development, including the early signs of autism spectrum disorders and other developmental disabilities, and to encourage developmental screening and intervention. Learn the Signs. Act Early. builds on familiar experiences of parents, such as monitoring their children's physical growth, and expands to social and emotional milestones such as how children speak, learn, act, and play. Just as taking a first step is a developmental milestone, so are smiling, pointing, and waving goodbye.

We know that when developmental delays are not recognized early, children cannot get the help they need. By increasing the awareness of autism spectrum disorders and other developmental disabilities and their signs and symptoms, we can increase early developmental screening, diagnosis and intervention. This means affected children can receive the help they need to enhance their development and improve the quality of life for them and their families.

To date, the campaign has reached more than 11 million health care professionals, parents, partners, campaign champions, and it is achieving its first goal—to encourage target audiences to “Learn the Signs” of autism spectrum disorders and other developmental disabilities. Outcome data show significant improvements in the percentage of parents who are aware of early warning signs of developmental delays, as well as increases in the number of pediatricians who agree that a child with an autism spectrum disorder can be diagnosed as early as the age of 18 months. Since the launch of the campaign, more pediatricians report that they regularly screen pediatric patients for developmental delays.

In November 2006, Learn the Signs. Act Early launched the childcare provider segment, targeting the more than 407,000 childcare facilities in the United States.

This new phase will provide free materials to help childcare providers and preschool teachers educate parents about child development and autism spectrum disorders.

#### FUTURE OPPORTUNITIES

CDC recognizes that parents want answers. If a child has an autism spectrum disorder, his or her parents want to know what caused it, the most effective intervention, and how they can lower their risks if they plan to have other children. We share their frustration at not having more answers about the causes and possible cure for the debilitating symptoms of autism and related conditions. That is why CDC continues to track the rates of autism spectrum disorders, research possible causes, and provide accurate information about identifying developmental concerns and seeking help during a child's early years of development.

CDC is positioned to bring surveillance, research, awareness and intervention activities to scale. Building on the encouraging success in these areas, CDC can continue answering important questions about prevalence and trends and can bring to bear population-based research tools in the effort to find answers about potential causes of autism spectrum disorders. The CDC can encourage the best known timely interventions for children and their families. Enhancing our programs would allow us to maintain surveillance in key sites and evaluate prevalence for different age groups, research potential causes more aggressively, and answer prevalence and trend questions faster. We can build on successes in educating the public about early intervention and education in our Learn the Signs campaign by continuing to develop and implement strategies to support parents, healthcare professionals and childcare providers in their efforts to Act Early when concerns are raised about autism spectrum disorders and other developmental disabilities.

Thank you for the opportunity to appear here today to discuss this important public health issue. Thank you also for your continued interest in, and support of, our activities on autism spectrum disorders. Together we hope to find answers for this very complex disorder.

I appreciate your longstanding support for our vision of healthy people throughout all stages of their lives and all facets of living. I will be happy to answer any questions you may have.

Senator HARKIN. Thank you, Dr. Gerberding, and I just mentioned, I am going to change the format since Senator Specter has to leave, I will go with Dr. Insel, then we will have some questions for the two of you before we bring the other people up.

Dr. GERBERDING. Thank you.

Senator HARKIN. Now, we turn to Dr. Thomas Insel, Director of the National Institute of Mental Health since September 2002. Dr. Insel received his B.A. and M.D. degrees from Boston University. Dr. Insel, welcome back to the committee.

#### NATIONAL INSTITUTES OF HEALTH

#### NATIONAL INSTITUTE OF MENTAL HEALTH

#### STATEMENT OF DR. THOMAS R. INSEL DIRECTOR

Dr. INSEL. Thank you, Senator Harkin and Senator Specter.

It's a real pleasure to be here, and I too would like to express my gratitude for the support that we've gotten from both of you, and your leadership positions over the years.

As you mentioned, the NIH budget has increased very significantly, in the case of autism, it's gone up, actually, almost five-fold since 1997, and that's only possible with your leadership and with your advocacy for bio-medical research.

I think in view of the time and the number of the things that we want to cover, you already have my written testimony, I think I will make my comments rather brief.

What I thought I would do is speak to what we actually know, that we're confident about at this point in time, and unfortunately, I can do that in less than 5 minutes, because it's a fairly short list.

So, what you have before you are what, I think, are the four most important points that we can use as a baseline for the knowledge-base. We can talk more about some of the specifics and some of the actual research, as we get further into the hearing.

The first point to make, and it may seem obvious, but it's actually a fairly complicated point, is that autism is a developmental brain disorder. Yes, it involves other organs of the body, and the gut is one that has been implicated, as you mentioned Senator Harkin, but it's important for us to focus on this as a brain disorder that evolves through development.

The reason I stress that is, because when you think about developmental brain disorders, it's not simply what happened, or where it happened, it's when it happened that may be really critical. So, much of what we need to understand is when the train goes off the tracks in brain development to result in the kinds of deficits that Dr. Gerberding mentioned—the difficulties in social reciprocity, the difficulties in language, the abnormal behaviors that are really key to autism.

It changes the way we think about this a little bit because it suggests also that there could be multiple causes that if they occur at the same point in time—and many of us think that that point may be prenatal—it sets up a trajectory that's abnormal, that leads to this very, as you mentioned, devastating disorder.

Point number two, you'll hear from constituents and you'll read in the press—is this really genetic? Is this really environmental? The answer is, it's both. That, with this disorder, as with so many of these developmental disorders that we study now, we've—in the scientific world—have gotten beyond the point of arguing between genes and environment, it's like the old nature/nurture debate. The debate now is about how genes and the environment interact to result in this disorder.

We do know there's an important genetic component, no question about that, from what we have from twin studies, but we also know that that doesn't explain the entire disorder. And it certainly wouldn't explain any potential increase in the prevalence—or increase, even, in the incidents—over the last decade.

So, lots of interest in what the environmental factors might be. But, to understand those, we will need to drill down, and get a very good understanding of who has the genetic risk to be responsive to that environmental factor. So, much interest now, in trying to understand the complicated interaction of those two factors.

Third, this is—as Dr. Gerberding mentioned—important to have early detection, early interventions. There are treatments that work—they don't work for all children. Perhaps 25 to 30 percent of children respond beautifully to behavioral interventions, but they respond best with early detection and early intervention, particularly before age 3. As Dr. Gerberding mentioned, many of these children aren't even diagnosed until sometime thereafter.

## PREPARED STATEMENT

Finally, current science more and more is telling us that this is not one illness. This is a group of disorders—much the way we think about hypertension, much the way we think about other classes of disorders in medicine. This is one—in the way that we perhaps once talked about mental retardation—it’s likely we’re going to find many, many disorders within this overall rubric. Increasingly, at NIH, we talk about “autisms” instead of “autism.” That is probably an important perspective to remember, as we begin to think about causes, and also about treatments.

Thank you, I look forward to your questions, and I look forward to the discussion, as well.

[The statement follows:]

## PREPARED STATEMENT OF DR. THOMAS R. INSEL

Good afternoon, Senator Harkin and members of the subcommittee, I am pleased to present a brief review of the research activities and accomplishments in autism research of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS). I deeply appreciate your continued support for our mission: making medical discoveries to improve health and save lives. In focusing today’s hearing on autism we will be discussing an urgent, critical public health challenge affecting many families.

## WHAT IS AUTISM?

Autism is a developmental brain disorder, with onset by 3 years of age. We now believe that autism includes a large number of disorders that share deficits in social behavior, abnormal communication, and repetitive behaviors. Autism in turn is part of a broader continuum of syndromes called pervasive developmental disorders, now more commonly known as autism spectrum disorders (ASDs). ASDs range in severity, with “classic” autism being the most disabling, while others, such as Asperger’s syndrome, produce milder symptoms. Among children at the more severe end of this spectrum, mental retardation, seizures, and self-injurious behaviors are common.

Current Centers for Disease Control and Prevention (CDC) estimates of the prevalence of ASDs are as high as 6.7 children per 1,000.<sup>1</sup> “Prevalence” refers to the number of affected individuals at a given point in time, essentially a snapshot. While prevalence estimates have increased many-fold since the early 1990s, it is unclear if there also exists an increase in “incidence”, which measures the number of new cases across time in the same population. It is unclear whether the rise in prevalence is due to a rise in incidence, better identification and awareness of the disorder, or both. A similar increase in prevalence has been observed in many countries outside of the United States, and in virtually every study, boys are three to four times as likely to have ASDs compared to girls.<sup>2</sup>

## WHAT CAUSES AUTISM?

There is much that remains unknown about the causes of autism. Scientific research has demonstrated that autism is highly heritable, as measured by concordance rates in twins. If one identical twin has autism, there is a 60–91 percent chance the other will also have it. For fraternal twins, the concordance for autism drops significantly, to 0–10 percent.<sup>3</sup> While higher concordance in identical twins is not proof of a genetic cause, approximately 10 percent of autism cases with a family history of ASDs are associated with genetic mutations.<sup>4</sup> Recently, a study of people with autism who did not have another family member also affected found approxi-

<sup>1</sup> Centers for Disease Control and Prevention. Prevalence of Autism Spectrum Disorders’ Autism and Developmental Disabilities Monitoring Network, 14 Sites, United States, 2002. Surveillance Summaries, February 9. MMWR 2007;56 (No. SS-1).

<sup>2</sup> Fombonne E. Epidemiology of autistic disorder and other pervasive developmental disorders. *J Clin Psychiatry*. 2005;66 Suppl 10:3–8.

<sup>3</sup> Veenstra-VanderWeele, J, Christian, SL, Cook, EH (2004) Autism as a paradigmatic complex genetic disorder. *Annu. Rev. Genomics Hum. Genet.* 5:379–405.

<sup>4</sup> Barton M, Volkmar F, *J Autism Dev Disord.*, 1998, 28(4):273–8.

mately 10 percent associated with spontaneous genetic mutations.<sup>5</sup> In addition, autism is frequent in children with several known genetic neurodevelopmental disorders, such as Fragile X, Rett Syndrome, or Tuberous Sclerosis Complex.

Identifying both the environmental and the genetic underpinnings of autism are critical first steps in bringing the full scientific power of modern neuroscience to bear on this complex set of disorders. We now have the genetic sequencing and neuroimaging tools that will permit a more thorough understanding of the neural substrates of autism. Indeed, what these scientific tools may tell us is that ASDs are illnesses with multiple causes and, much like hypertension or cancer, may be treated and possibly prevented through interventions on multiple fronts. Importantly, these new scientific approaches will enable us to develop new diagnostic tests and rational therapies based on the biology of the illness that will permit us to detect and treat ASDs in much the same way as other medical conditions.

#### HOW IS RESEARCH COMBATING AUTISM?

Combating autism is a collaborative effort, involving several NIH Institutes, the CDC, and public-private partnerships with advocacy organizations. NIH has increased funding for autism nearly five-fold since 1997, to support broad research efforts across genetic, neuroscience, environmental, and treatment studies. Already, this investment is bearing important results for better understanding the brain abnormalities in autism, improved methods for early detection, and refining interventions for optimizing daily functioning. NIH continues to fuel this research momentum, most recently with program announcements encouraging research on the characterization, genetics, pathophysiology, and treatment of autism and related neurodevelopmental disorders, as well as requests for applications to collect data and biomaterials from autistic individuals and their relatives for use in genomic, basic, translational neuroscience research, and clinical trials. Here I will note just a few of the recent developments that offer hope for families struggling with autism.

The recently established NIH National Database for Autism Research (NDAR) for the first time provides an open-access platform to facilitate sharing of raw research materials, foster collaborations and public-private partnerships, and enhance rapid dissemination of research findings into clinical practice. It is envisioned as a dynamic, federated system, with improvements and updates being added routinely to meet the most critical and valuable needs of the research community.

Early detection is important for improving outcomes. The National Institute of Child Health and Human Development (NICHD) and the National Institute on Deafness and Other Communication Disorders (NIIDCD) continue to partner with Autism Speaks to support the High Risk/Baby Sibling Research Consortium, an effort to improve early detection and diagnosis. The Consortium's primary project is to identify factors that may influence recurrence rates of ASDs and broader developmental outcomes in infant siblings of individuals with ASD. Recruitment of sibling and comparison groups is on target and database development and data analysis have begun.

Responding to the urgent need for an amplified autism effort, the National Institute of Mental Health (NIMH) created a new, integrated autism research program in its intramural laboratories in Bethesda. Several new clinical trials were launched in 2006 that provide opportunities for rapid progress in defining the biological and behavioral characteristics of different subtypes of ASDs and examining effects of innovative treatments for autism. Intramural researchers are also collaborating with M.I.N.D. (Medical Investigation of Neurodevelopmental Disorders) Institute and University of California at Davis scientists in a pilot of the first large-scale effort to provide a comprehensive biomedical and behavioral characterization of 1,500 individuals with autism spectrum disorders. The goal of this Autism Phenome Project is to identify the many subtypes of autism, providing guides for personalized approaches to treatment.

In addition to these efforts, NIH is striving to identify and understand environmental influences as potential causes of ASDs. The National Institute of Environmental Health Sciences (NIEHS), in partnership with the Environmental Protection Agency (EPA), supports research through Centers that focus on this important question. One of the centers, at the University of California at Davis, is conducting the first large population-based, epidemiologic case-control study of children with autism. In addition, the National Institute of Neurological Disorders and Stroke (NINDS) is providing support for a five-year prospective epidemiological study of a large Norwegian birth cohort of 75,000 women and their babies. The study, which

<sup>5</sup>Sebat et al, Strong Association of De Novo Copy Number Mutations with Autism. *Science*. 2007 Mar 15; [Epub ahead of print].

we expect to include up to 500 children with ASDs, will examine the contribution of genetic and environmental factors to the development of autism and other neurodevelopmental disorders; these factors include infection history, low birth weight, dietary and environmental exposure to methyl-mercury, and vaccination history.

Solving the mysteries of autism will require scientists from many disciplines working together on common problems. To launch a broad, multidisciplinary attack on autism, NIH recently created an ambitious, integrated program in order to maximize coordination and cohesion of NIH-sponsored efforts—the Autism Centers of Excellence (ACE), for which the first grants will soon be issued. Research projects will focus on identifying biological and environmental causes and preventive interventions for autism, as well as improved pharmacological and behavioral treatments. These Centers will be coordinated through NDAR and will represent the first integrated, national research effort for this disorder, with an estimated funding level of \$25 million per year.

#### HOW CAN WE CURE AUTISM?

While there is not a proven biological treatment for the core symptoms of autism, it is generally agreed that early identification and behavioral intervention is beneficial. Thirty years of study have shown the value of employing behavioral methods to enhance social skills, language acquisition, and nonverbal communication. Such gains may be evident in individual responses to particular behavioral techniques in the short term ? in as little as a matter of months.

Yet even in studies where children have received the largest gains, outcomes are variable, with some making significant progress and others advancing quite slowly or not at all. A multi-study analysis of the effect of treatment indicates that behavioral treatments are most successful when they begin early, are intensive, and highly structured. Current NIH-funded research includes studies for toddlers that involve parents in the delivery of interventions at home, immediately after diagnosis, as opposed to waiting for community or other services to begin.

While medications are useful for some of the accessory symptoms of autism, such as self-injurious behaviors, we lack medical treatments for many of the core symptoms, such as social deficits. As we discover more about the causes and the mechanisms of autism, we expect to develop a new generation of medications to help children and adults affected with ASDs. Ultimately, our goal is prevention, based on early detection of risk, understanding environmental factors that increase or decrease symptoms, and development of effective interventions before behavioral and cognitive deficits appear.

#### THE FUTURE

The Combating Autism Act of 2006 (Public Law 109–416) was signed into law on December 19, 2006. Plans are underway to implement the provisions of this law, which calls for the establishment of a new Interagency Autism Coordinating Committee (IACC) to coordinate all efforts within HHS concerning autism spectrum disorders, including the development of a strategic plan that sets research funding priorities. Thus, broad collaborative partnerships involving government, private industry, public and educational institutions, and families of those with autism will continue to fuel the vital research endeavors that will reveal the mysteries of this disabling disorder and lead to prevention and effective treatments.

Autism is a serious, disabling developmental illness that affects many families in this country. Research is our best hope for making a difference for these families. Given the complexity of the disorder, answers will not be as simple or as quick as we wish, but NIH is committed to bringing the best minds and the best tools to ensure that we get the correct answers that will lead to the best treatments. I therefore appreciate the interest of the members of this Subcommittee on autism research. I look forward to answering your questions.

Senator HARKIN. Thank you very much, Dr. Insel, and Dr. Gerberding.

I'll yield to Senator Specter.

#### BUDGET ALLOCATIONS

Senator SPECTER. Well, thank you very much, Mr. Chairman for accommodating my schedule.

Dr. Insel, the funding for autism has risen, as I noted, from \$27 million in 1998, to a projected budget in 2008 of \$107,870,000—that's actually about a \$400,000 decrease from last year.

The allocation for autism is substantially less than the allocation for other major research activities, of the National Institutes of Health. It is obviously a very serious disorder, striking 1 children out of 150. With the New Jersey statistics, which are said to be more representative of the national average, being 1 child out of 97.

There is total discretion left within the National Institutes of Health to make the allocation of the \$29 billion which is appropriated by Congress, and that is so we do not, so-called "politicize" it—we don't make political decisions, but leave it up to the scientists. But, I think within the range of following that very important principle, it is not inappropriate to raise a question. When you take a look at the budgets for cancer—and I'm all for cancer research—or the budgets for heart disease, they range into, close to \$5 billion for cancer. How are the allocations made, to have the \$107 million, roughly, which is a very, very small part of the NIH budget, compared with other research budgets?

Dr. INSEL. Well, as you mentioned, much of this is driven by the science, it's investigator-initiated for the largest part of what we're currently doing.

In the area of autism, unlike many of the other areas that you mentioned, and many areas in medicine, in general, we do have an organization in place to begin to think about how best to deploy the funds that we have. That's this Inter-agency Autism Coordinating Committee, that meets twice a year, includes public members as well as members of several Federal—

Senator SPECTER. How about the basic decision as to how much goes to the National Cancer Institute, for heart research, contrasted with \$107 million for autism?

Dr. INSEL. So, how is the decision for the envelope, the overall envelope, made for autism, versus other priorities at NIH?

Senator SPECTER. Start there.

Dr. INSEL. Right. So, I would have to again, give you the answer that Dr. Zerhouni has given when you've asked him a similar question, that it's a combination of public health needs and scientific priorities. This case, the public health—

Senator SPECTER. Public health, what?

Dr. INSEL. Public health needs. There, and as you mentioned, the public health urgency here is obvious, to all of us. This is a problem which is increasing in everyone's radar screen, this is, without question, a much bigger issue for us than it was 5 years ago—

Senator SPECTER. I've got to move on to some other questions because of limited time, but you will be here for the entire proceeding today, and maybe when you hear some of the parents, you'll have a little different view of the urgency of a greater allocation. That is a judgment which NIH is going to have to make.

Autism is characterized—as the experts have written—by three distinctive behavior difficulties, with social interaction, display problems with verbal and non-verbal communications, and the exhibition of repetitive behavior, or narrow obsessive interests.

It is well-known, Dr. Gerberding, and you've noted it, that the early detection of these behavioral disorders can produce improvements. What should parents do as soon as they observe some of these behavioral disorders? Your comments here will get some substantial coverage on C-Span—what advice would you give to parents who—well, let's start with something more concrete than the definition I've just given you, which is pretty high-falluting. What should parents look for, specifically, in lay terms?

Dr. GERBERDING. You know, when you have a child, you're used to thinking about, what is its weight, what is his or her height, what is their head circumference—we're used to measuring those physical development milestones. But, there are behavioral milestones just like that.

By early age, a child ought to be able to make eye contact, if you play peek-a-boo with a child, they should engage your attention, they can repeat after you—

Senator SPECTER. Okay, eye contact—eye contact is not made. Give us another easy-to-understand symptom.

Dr. GERBERDING. If a child is unable to repeat simple motions, in other words, if you clap your hands, a young child ought to be able to repeat your pattern—we have these laid out by age, just like you would lay out weight by age—

Senator SPECTER. Laid out where, are they on a website?

Dr. GERBERDING. They are, absolutely, on the CDC website, [www.cdc.gov](http://www.cdc.gov), they are posted prominently in pediatricians' offices around the country—

Senator SPECTER. Can you give us a couple of other simple illustrations?

Dr. GERBERDING. I would be happy to give you a whole little chart, because I have here—

Senator SPECTER. Why don't you repeat them, so people can hear you on C-Span?

Dr. GERBERDING. Okay, I'd be happy to.

I'm quoting from Newsweek magazine, because I thought they did a terrific job in one of the articles here of laying them out.

By 7 months, a normal child ought to be able to turn its head when its name is called and smile at another person. If your children is a year old, usually they can wave "bye-bye" and they can make sounds like "mom" and "dad" or "ma" and "da" and they can clap when you clap.

At 18 months, a child ought to be able to pretend, like pretend to talk on a telephone, or to look at objects when you point to them. By 2 years, a child ought to be able to make simple sentences with several words in a phrase, and follow simple instructions, and, I think most importantly, engage socially with other children, they'll play—

Senator SPECTER. Let me interrupt you, at that point—to ask you what should a parent do to try to deal with the issue of the behavioral disorder as soon as it noted?

Dr. GERBERDING. If a child is—if a parent is concerned about their child's development, the pediatrician or the family doctor is absolutely the first place to go, and we have really been pushing information—about 85,000 kits have gone out to pediatricians around the country. So, parents go in, express their concern when



they're bringing the child in for well-baby care, or for the immunization clinic visit, and the most important thing to the parent is, don't give up. If the doctor says, "Oh, no, maybe your child is just a little slower to catch on," ask for the doctor to do a screen, and if there's any worry, make sure that you get a second opinion, or ask the child to be seen by someone with more expertise.

Senator SPECTER. But, what kind of a screening?

Dr. GERBERDING. It's a developmental screening, and typically the doctor will ask the child to go through some of the same activities that I just mentioned to you, they'll conduct a developmental assessment.

#### NEW DIRECTIONS FOR RESEARCH

Senator SPECTER. One final question, because I don't want to go too long, and out of sequence.

Dr. Insel, if more funds were available, suppose we're able to increase NIH funding so all the boats would rise, where would those additional research funds be directed to the kinds of problems that Dr. Gerberding has described?

Dr. INSEL. Well, there are at least three very urgent problems that we would like to do more of, and do them faster. One would be very similar to what Dr. Gerberding is describing, looking at the tools for early detection or early diagnosis, early intervention—much of that's going through what we call our "baby sibs" project, looking at children at risk, and studying them in a very comprehensive way.

Second area, very important, is to lay out what we call the "autism phenome" project, the idea of being, the phenome is like phenomenology, understanding the full spectrum of this disorder, and all of the components, so that we can get a sense of, what are the sub-groups? That this is many disorders, if it's 10 disorders, what are they? How do we diagnose them? How do we treat them?

Third area that's very important, it doesn't sound so sexy, perhaps, but is developing a database, which we call the National Database for Autism Research—we have such a database that brings the entire research community, as well as, potentially, families together. It's a federated database, which means it will take other databases that are out there and bring them in for imaging, genetics, and clinical information.

What we'd like to do—we have this now, it went live on April 2, but it's still very restricted—we need to grow that, and we need to make this a sort of electronic meeting place for both families and scientists from across the country, to try to get the best information possible about autism.

Senator SPECTER. Well, in conclusion, let me just make an observation or two.

Dr. Gerberding, I think the website is fine. If people write to you, not having access to the website, or not understanding the website, is CDC in a position to respond to parents by providing this kind of a graphic illustration of symptoms and signs to look for, perhaps even a copy of what appears in Newsweek, under the caption, Babies and Autism?

Dr. GERBERDING. We would be happy to get information to parents and to their doctors, and we can do that by a variety of means, absolutely.

Senator SPECTER. Dr. Insel, when you take a look at your priorities, I know you'll pay attention to all of them, and I know you'll listen carefully to what you hear today.

Senator Harkin and I, and some of the others on the committee are magnets for a lot of comments from parents, because they see what the committee has done. It is accurate to say that I hear a disproportionate comment from parents whose children have the autism disorder. I hear a lot of people—and a lot of my friends are dying of cancer—and I know a lot of people with heart conditions. I've seen a fair amount of that in the mirror. But, on a numerical basis, I hear, just a lot about autism, and maybe that comes because we advertise on this Subcommittee with what we do for NIH, but I'd like to see it get a little more attention.

Senator Harkin, thank you for your courtesy.

Senator HARKIN. Thank you, Senator Specter.

Again, just another little change because the clock is ticking, and I want to hear the testimony of others. I would ask if you two could maybe, give us some bookends here, Dr. Insel on one side, Dr. Gerberding, because I have questions for you, I'm sure other Senators do. But I'd like to ask our second panel to come up, if I could, at this time.

Marguerite Colston, Dr. Judith Favell, Mr. Bob Wright, and Mr. Bradley Whitford.

Again, welcome to the committee, and as I said at the beginning, all of your statements will be made a part of the record in their entirety, and I'd appreciate it if you'd just sort of sum up for us, the essence of your statements, and I'll go in the order in which I had called people up.

First, we'll recognize, Marguerite Colston, Communications Director for the Autism Society of America. More importantly, she's a parent of a child with autism, her 6-year old son, Camden. Welcome to the committee, and please proceed.

**STATEMENT OF MARGUERITE COLSTON, DIRECTOR OF COMMUNICATIONS, AUTISM SOCIETY OF AMERICA, BETHESDA, MARYLAND**

Mrs. COLSTON. Thank you. I'd like to thank Chairman Harkin, and Senator Specter and the members of the subcommittee for giving me the opportunity today to share my experience of living with a child on the autism spectrum. I also wanted to say thank you very much to you and Senator Specter for those very important questions you asked.

It is truly an honor to be asked to speak to you today, and I hope I can convey some of the needs, hopes and dreams of the more than 1 million families in America who are affected today.

As you mentioned, I am the Director of Communications for the Autism Society of America, and I am the mother of two children, including a 6½ years old son with autism. My son, pictured here, is Camden, this is Camden.

My son has a disorder with no known cause, and no known cure. You have, at your disposal today, the best experts on researching causes and cures. But I am here today to tell you about the very

important space between causation and cure, the space that Camden and I occupy, that is, how we live with autism.

Because that important space is occupied today by 500,000 children, and at least as many adults, families desperately need Federal leadership and funding for autism today.

Camden is on the severely affected end of the spectrum. He cannot talk, has some cognitive delays, major attention deficits, and suffers significant social and behavioral challenges. As you can see, though, he's also adorable, and he has a much larger capacity to learn than any of us imagined.

Like many parents, I was told that autism was not treatable, and that the best thing I could do for Camden was to prepare myself and my family for the idea that he would never be independent. Experts told me that information when he was only 2½ years old.

Today, my little boy, who for years did not turn to his name or react to games, now grabs my hand after dinner, and takes me to the refrigerator for his nightly ice cream. When the school bus comes every morning, he walks on with a grin and he finds his seat. Camden does not make these developments naturally, but through intensive therapy, Individualized Education Plans, high medical costs, and a sizable team of dedicated professionals.

In many respects, my story is typical. Camden was diagnosed with autism when he was 2½. However, I was lucky that Camden was born with other medical ailments, and very low muscle tone, because unlike most children with autism, Camden began receiving Early Intervention services from our county when he was just 6 weeks old. Even though we only received 4 hours per week of Early Intervention, that program was the reason Camden can chew, sit up, and walk onto a school bus today.

Like most families, I had to wait 12 long months to get an appointment with a developmental pediatrician, when my pediatrician expressed concerns about Camden. My wait times for his specialists continue to be 12 to 18 months, so we rely heavily on the public educational services we receive, thanks to the IDEA Act, and thank you for your support of that.

As I think about it, however, I am still very concerned about what would happen to Camden, once the school bus stops coming. Camden, and most children and adults with autism, is going to need a lifetime of supports and services. Even if he is able to speak someday, he will need training to prepare him to enter the workforce, assistance with transportation and housing, access to health care, and a range of other services to allow him to live as independently as he is able.

Unlike most parents, I consider myself to be a very privileged American. I received a great education, I have a good job, I own my own house, and I have a wonderful and supportive family, and several of them are here today. I can afford a small amount of respite care and private therapy. So, I have to wonder, if I couldn't get my son diagnosed before 2½, and if it takes me 18 months to see a doctor, and if I can't afford truly comprehensive services, than what is happening to the average American with a child on the autism spectrum today?

If I accepted that autism was not treatable, and Camden had no hope, what do others do? What happens after Camden turns 22,

and the federally-mandated disability services end? What are we going to do about this?

One of the things we can do for Americans living with autism is fund the Combating Autism Act, and encourage the resulting research to be treatment-guided, not just causation specific. Funding the CAA also means funding the Inter-Agency Autism Coordinating Committee, and they have a wonderful roadmap for services. We can also pass and then fund the Autism Services bill put forth by Senators Clinton and Allard last month, and which the House introduced today.

As a parent, I strongly support those bills. As a staff member for the Autism Society, I can assure you that we, our chapters and our members will work tirelessly to advance legislation that includes research services and supports for individuals with autism.

I love my son, Camden, with every bone in my body. I know there are a million Camden's out there whose needs are not being met, and whose families are in crisis. Regardless of the cost, we need to support coordinated Federal autism solutions today. Only then will we be able to optimize the potential of each child with autism, and provide them opportunities for success in their communities.

#### PREPARED STATEMENT

Being here today and being heard by the U.S. Senate gives me an enormous sense of hope that I never dared to have. With your help and your leadership, I may start to hope for Camden, the same hopes I have found I have for my neuro-typical daughter, Theresa—that he will be provided the opportunity to be a happy, productive member of his community.

I'd like to thank the committee again, for hearing me, and for support of this legislation.

[The statement follows:]

#### PREPARED STATEMENT OF MARGUERITE KIRST COLSTON

I would like to thank Senator Harkin and the members of this subcommittee for giving me the opportunity today to share my experience of living with a child with autism. It is truly an honor to be asked to speak to you today, and I hope I can convey some of the needs, hopes and dreams of the more than 1 million families in America today who are affected by autism.

My name is Marguerite Kirst Colston. I am the Director of Communications with the Autism Society of America and I am the mother of two children, including a 6-year-old son with an autism spectrum disorder. My son, pictured here, is named Camden.

As you have heard today from the panelists, my son has a disorder with no known cause and, as I have been told by many doctors, no cure. You have at your disposal the best experts on researching causes and cures, but I am here today to tell you about the very important space between causation and cure—the space Camden and I occupy—that is: how we live with autism. Because that important space is occupied today by 500,000 children, and at least as many adults, families desperately need federal leadership and funding for autism.

Camden is on the more severely affected end of the autism spectrum, by which I mean he cannot talk, has some cognitive delays, major attention deficits and suffers significant social and behavioral challenges. As you can see, he is also adorable and, as I am finding, has a much larger capacity to learn than any of us imagined.

Like many parents, I was told that autism was not treatable, and that the best thing I could do for Camden was to prepare myself and my family for the idea that he would never be independent. Experts told me that when Camden was 2½. Today, my little boy, who for years did not turn to his name or react to games, now grabs my hand after dinner and takes me to the refrigerator for his nightly ice cream.

When the sun sets, he runs to take a bath. When the school bus comes every morning, he walks on with a grin and finds his seat. Camden does not make these developments naturally, but through intensive therapy, individualized education plans, high medical costs, and a sizeable team of dedicated professionals helping us along.

In many respects, my story is typical. Camden was diagnosed with an autism spectrum disorder when he was 2½. This diagnosis came after 2½ years of emerging symptoms, disappearing interaction, specialist referrals, hundreds of doctor's visits, several hospitalizations—and many missed clues. I was “lucky” that Camden was born with other medical ailments and very low muscle tone, because unlike most children with autism, Camden began receiving Early Intervention services from our county when he was just 6 weeks old. Even though we only received 4 hours per week of Early Intervention, that program was the reason Camden can chew, sit up, and walk onto his school bus today.

Like many parents with children with autism, I had to wait 12 long months to get an appointment with a developmental pediatrician when my pediatrician expressed concerns about Camden. My wait times for his specialists continue to be 12 to 18 months in duration, so we rely heavily on the educational services with receive in our public school system thanks to IDEA Act. I want to say a heartfelt thank you to you, Senator Harkin, for your strong support of legislation like this.

As I think about it, however, I am still very concerned about what will happen to Camden once the school bus stops coming. Camden—and most children and adults with autism—is going to need a lifetime of services and supports. Even if he is able to speak one day, he will need training to prepare him to enter the workforce, supports in his job, assistance with transportation and housing, access to health care, and a range of other services to allow him to live as independently as he is able.

Unlike most parents, I consider myself a very privileged American. Like the rest of the panelists here today, I received a great education, have a good job, own my own house, and have a wonderful and supportive network of family. I can afford a small amount of respite care and private therapy. I stand up for my rights and have the confidence to ask questions of the medical and educational communities. But I have to wonder: if I couldn't get my son diagnosed before 2½, and if it takes me 18 months to get into a doctor, and I can't afford truly comprehensive services, then what is happening to the average American with a child with autism today? If I accepted, in a desperate moment, that autism was not treatable and Camden had no hope, what do others do in their sorrow? What happens after he transitions away from the education system? And, what are we going to do about this?

One of the things we can do for Americans living with autism is fund the CAA and encourage the research done here to be treatment-guided, not just causation-specific. Funding the CAA also means funding the Inter-Agency Autism Committee, which could serve parents tremendously by coordinating Federal autism services and research along a road map that will help us now. This is why the Autism Society of America encouraged tens of thousands of members to support CAA and why we also support legislation like the reauthorization of the IDEA act, the Lifespan Respite Act, and S-CHIP funding.

Last month, Senators Clinton and Allard took a historic step toward empowering families and individuals with autism by introducing legislation to build and support a services infrastructure for autism spectrum disorders. Unfortunately, our current system for assisting adults with disabilities is stretched way too thin. Providers do not have the capacity to meet the ever increasing number of individuals with autism. We must do more to identify best practices for serving people with autism spectrum disorders. The House companion bill will be introduced today.

As a parent I strongly support this legislation. As a staff member for the Autism Society of America, I can assure you that we will work tirelessly to advance this bill, and other measures that improve services and supports for individuals with autism. I love my son Camden with every bone in my body, and I know there are a million Camdens out there whose needs are not being met and whose families are in crisis. Regardless of the cost, we need to support coordinated federal autism solutions today. We will then be able to optimize the potential of each child with autism and provide them opportunities to for success in their communities.

Being here today and being heard by the U.S. Senate, gives me an enormous sense of hope that I never dared to have. With your help and your leadership, I may start to hope for Camden the same hopes that I have for my “neurotypical” daughter Theresa—that he will be a happy, productive member of his community in his way, some day. Thank you.

Senator HARKIN. Thank you very much. That is very poignant and heartfelt testimony.

Next, we turn to Dr. Judith Favell, CEO of AdvoServ, a multi-State network of treatment programs for children and adults with developmental challenges. Dr. Favell received her Bachelor's Degree in Psychology from Western University, and her Ph.D. from the University of Kansas, out my way. Dr. Favell, welcome to the committee, please proceed.

**STATEMENT OF DR. JUDITH E. FAVELL, CHIEF EXECUTIVE OFFICER, ADVOSERV, EXECUTIVE DIRECTOR, THE CELESTE FOUNDATION, MOUNT DORA, FLORIDA**

Dr. FAVELL. Thank you, Mr. Chairman.

I'm also executive director of the Celeste Foundation, and a member of the Professional Advisory Board for the Autism Society of America.

During my nearly 40-years' career as a behavior analyst and as a psychologist, I have devoted myself to the field of autism, and developmental disabilities.

Now, during this period, I've specialized in the treatment of behavior problems such as self-injury and aggression that sometimes associated with these disorders. It is on the delivery of such treatment services that I'm focusing my comments today.

While research on the cause and course of autism continues, while the incidents and prevalence is tracked, while basic research on the underlying mechanisms of the disorder is conducted, we cannot lose sight, as just has been said, of the 1.5 million children and adults today living with autism who need help today. Today they are seeking services that will allow them to gain the skills and resolve the behavioral challenges that will enable them to live and enjoy the fullest life possible.

Fortunately, across the last years, major advancements have been made in the development of educational and behavioral strategies to teach these skills and to treat these problems. These methods have been tested across, literally, decades of scientific research, and confirm that children and adults with autism can indeed be helped in meaningful and substantial ways.

They can learn to communicate, they can learn to care for themselves. They can achieve academic and job goals. They can reciprocate love with friends and family. Likewise, people experiencing autism can engage in behavioral problems that hurt themselves, or harm others. In short, effective treatment and teaching methods designed to help people with autism, notably those based on learning theory, and applied behavior analysis are available today, and each day are becoming more effective with continued research.

So, this picture is a decidedly optimistic one. However, effective methods of instruction and behavioral treatment are clearly not enough. To impact the lives of people with autism, an equally important issue must be addressed, and that is, how to actually make these services available to people who need them. There exists not just a gap, but a chasm, between what we know, and what consumers actually receive.

For example, we know as has been said, that to be optimally effective, services should begin as early in a child's life as possible, and be intensive, that is, encompass as many hours as possible. Yet, as we hear, families lose precious months—years—waiting for

services, and then too often must settle for a fraction of what their child needs.

Too often, then, those very services are not available when and where they are actually needed—at bedtime, during meals, or in the midst of the meltdown during the weekend. Needs of people with autism do not conveniently conform to professional appointments or clinic hours. Support may be needed any time, day or night.

Further, we know that to be effective, and to produce positive outcomes, services need to be provided by qualified caregivers, and yet, despite widespread training of families and service personnel, despite extensive recruitment of professionals to the field of autism, there remains a serious shortfall of qualified professionals to guide the treatment process.

Thus, though we know a great deal about how to help, we must increase the accessibility and availability of these services, to ensure that people with autism actually receive that help.

If we're truly to ensure that services are available early, in sufficient amounts, and targeted when and where needed, traditional solutions, for example, increasing training of professionals—though important—is simply not sufficient. To meet the challenge, new service models must be developed.

Our own work at the Celeste Foundation provides an example of possible new approaches to improving services, both their availability, and potentially their cost-effectiveness. From support from the Department of Education and the States within which we conducted this project, we recently completed a demonstration project, investigating the use of tele-health systems to provide professional services directly into homes.

Now, in this model, after a brief period of on-site training, families were linked to professionals via an interactive video system that enabled live, real-time teaching, consultation and support directly into the home when and where it was needed. Through this tele-health model, families received help teaching their child, coping with their challenges, from professionals who might be located hundreds, even thousands of miles away, ensuring rapid and responsive assistance, regardless of the distance involved.

This demonstration, utilizing technology developed by the CNOW Organization, proved to be an extremely effective and reliable vehicle for aiding families and children with autism.

Children learned and maintained a wide array of skills from communication, to toilet training to eating green beans. Parents reported relief from stress, and an improvement of quality of life as a function of having support available to them on an ongoing basis, and families and professionals alike affirmed the effectiveness of this method of facilitating services, and its ease of use.

The following brief news feature provides a graphic picture of the benefits of the model involved, of using tele-health systems for service delivery, and it features Josh Cobbs and his family, who is with us today.

Work such as this by the Celeste Foundation, demonstrating the efficiency and effectiveness of utilizing tele-health to facilitate services exemplifies the type of innovative approach that we must pursue, if we are truly going to meet the ever-increasing needs of chil-

dren, and adults, and their families with autism, bridging that chasm between knowledge and practice, moving services from the paper to the people.

#### PREPARED STATEMENT

I ask all in a position of influence, certainly including the distinguished members of this committee, to support efforts to find innovative methods of service delivery for all of those on the spectrum, including my grandson, Alex, so that they may receive the very best we have to offer, and lead the brightest future possible.

Thank you.

[The statement follows:]

#### PREPARED STATEMENT OF DR. JUDITH E. FAVELL

##### "SEEKING INNOVATIONS IN SERVICE DELIVERY"

Good afternoon, Mr. Chairman and members of this distinguished committee. My name is Dr. Judith Favell. I am CEO of AdvoServ, Executive Director of the Celeste Foundation, and a member of the Professional Advisory Board of the Autism Society of America. I have devoted my nearly 40-year career as a behavior analyst and psychologist to the field of autism and developmental disabilities. During this period I have specialized in the treatment of problem behaviors such as self-injury and aggression which can be associated with autism. And it is on the delivery of such treatment that I focus my comments this afternoon.

While research on the cause and course of autism continues, while its incidence and prevalence is tracked, while basic research on the underlying mechanisms of the disorder is conducted, we cannot lose site of the one and a half million children and adults who are now living with autism, and who need help now. Today they are seeking services that will help them gain the skills and resolve the behavioral challenges that will enable them to enjoy the fullest life possible.

Fortunately, across the last years, major advancements have been made in developing educational and behavioral methods to teach these skills and treat these problems. These methods, tested through decades of scientific research, confirm that children and adults with autism can be helped in meaningful and substantial ways. They can learn to communicate, to care for themselves, to achieve academic and job goals, to reciprocate love with friends and family. Likewise, people experiencing autism need not engage in behavior problems that hurt themselves or harm other people. In short, the treatment and teaching methods designed to help people with autism, notably those based on learning theory and applied behavior analysis, are available today, and each day are becoming more effective as a result of ongoing research. This picture is an optimistic one. However, improving these methods of instruction and treatment is not enough. To impact the lives of people with autism, an equally important issue must be addressed: how to actually make these services available to people who need them.

There exists not just a gap, but a chasm between what we know and what consumers receive. For example, we know that in order to be optimally effective, services should begin as early in the child's life as possible and be intensive, encompassing as many waking hours as possible. Yet families lose precious months or years waiting for services, and then must settle for a fraction of the help that their child really needs. Too often, these supports are also not available when and where they are needed, for example at bedtime, during meals or in the midst of a weekend meltdown. The needs of people with autism do not conveniently conform to clinic hours or professional appointments. Support may be needed at any time, day or night.

Further, we know that effective services and positive outcomes for people with autism depend on qualified caregivers, and yet despite widespread training of families and service personnel and extensive recruitment of professionals to the field of autism, there remains a serious shortage of qualified professionals to guide the treatment process.

Thus, though we know a great deal about how to help, we must now increase the accessibility and availability of these services, to insure people with autism actually receive that help. If we are to truly meet this ever expanding need, if we are to insure that services are available early, in sufficient amounts, and targeted when and where they are most needed, traditional solutions such as increased training of pro-



professionals are simply not enough. To meet the challenge, new service delivery models must be explored.

Our own work at the Celeste Foundation serves as an example of possible new approaches to improving the scope and cost-effectiveness of delivering services to people with autism and their families. With support from the Department of Education we have recently completed a demonstration project investigating the use of telehealth systems to provide professional services directly into homes. In this model, after a brief phase of on-site training, families were linked to professionals by an interactive video system that enabled live training, consultation and support directly into the home when and where it was needed.

Through this telehealth model, families received help in teaching their children and coping with their challenges from professionals located hundreds of miles away, insuring rapid and responsive assistance. This demonstration, utilizing technology developed by the Cnow organization proved to be an extremely reliable and effective vehicle for helping families and their children. Children learned and maintained skills ranging from communication to toilet training, parents reported relief from stress due to the availability of support, and families and professionals alike affirmed the effectiveness and ease of using the system. This very brief news feature provides a more graphic picture of the model and benefit of using telehealth to facilitate services.

Work such as this by the Celeste Foundation, demonstrating the efficiency and effectiveness of utilizing telehealth technology in service delivery, exemplifies the type of innovative approach we must pursue if we are to truly meet the ever increasing needs of children and adults with autism, bridging the current chasm between knowledge and actual practice, moving services from the paper to the people. I ask all those in a position of influence, including members of this distinguished committee, to support efforts to find innovative solutions to service delivery, so that those living with autism now will receive the best we have to offer, leading to the brightest futures possible.

Senator HARKIN. Well, thank you very much, as I said in my opening statement, I hear two pleas from families with autistic children. One, find a cure, but help us now. So many people that, they just don't have the ability to have someone come visit them every day to tell them what to do. I'll have more questions about that later, but I just thought—that's really the first time I've seen that clip, I'd heard about it, since it did take place in Iowa, I'd heard about it.

So I'll have more to ask you about that when we get into our formal questioning period.

Dr. FAVELL. Certainly.

Senator HARKIN. Mr. Bob Wright, Chairman of the Board of NBC Universal, the Vice Chairman of the Board and the Executive Officer of the General Electric Company. Mr. Wright, along with his wife, Suzanne, co-founded Autism Speaks.

Mr. Wright is a graduate of the College of the Holy Cross, received his law degree from the University of Virginia School of Law.

Mr. Wright, again, I thank you for your leadership in this area, and for co-founding Autism Speaks, and again, your statement will be made a part of the record in its entirety, and please proceed as you desire.

**STATEMENT OF ROBERT C. WRIGHT, CO-FOUNDER, AUTISM SPEAKS, FAIRFIELD, CONNECTICUT**

Mr. WRIGHT. Mr. Chairman, thank you very much for having us here.

Our grandson was diagnosed in 2004, at just 2 years and 3 months, and we were helpless. He was potty-trained, he spoke, he was very active, he was apparently a very normally-developing child, and everything slipped away from him. We were helpless as

we watched him slip away into this cruel embrace of a disorder. My wife, Suzanne, likes to call it kidnapping, as if someone had taken Christian who was meant to live, yet he was taken away, and we got nothing back, and there's no way to restore him back to his family—he's a little prisoner.

Since that diagnosis, we embarked on a mission to learn as much as we could about autism. We received, Christian received the best therapies and treatments that were available, but we discovered, however, that there are scarce resources for parents dealing with autism, and how thin the knowledge base is on the whole issue.

We had so many questions, and instead of answers, we were confronted with a bewildering array of theories and guesses.

Here's what we do know about autism. The numbers that Dr. Gerberding talked about, 1 in 150 children in the United States, 1 in 94 boys, that's the ratio. A decade ago, the experts estimated the prevalence in autism to be 1 in 2,500.

This year, more children will be diagnosed with autism than with AIDS, diabetes, and cancer combined. Autism costs the society, American society, approximately \$35 billion in direct and indirect expenses each year, according to a Harvard School of Public Health study. Caring for a child with autism can cost over \$3 million over a person's lifetime, those are the estimates.

Frankly, Mr. Chairman, we were shocked that a disorder this prevalent commands so little in terms of resources devoted to research and treatment when compared to other, less common, disorders.

For example, leukemia affects 1 in 25,000 people, children, but receives \$300-plus million a year of support from the NIH. Pediatric AIDS affects 1 in 8,000, and it's about \$400 million a year. And autism affects 1 in 150, and the funding level is approximately \$100 million.

To help close this gap, we launched Autism Speaks in February of 2005 to help raise the funds that would quicken the pace of research. We worked—and together we worked with literally thousands of families affected by autism, to introduce, and pass, and have the President sign the Combating Autism Act.

This is an historic act, it is considered by some to be the most comprehensive piece of single-disease legislation ever passed in the U.S. Congress. It authorizes \$920 million over 5 years for research and autism surveillance, awareness, early identification, and authorizes a 50 percent increase in the Department of Health and Human Services spending on autism.

For fiscal year 2008, the Combating Autism Act authorizes a spending level of a total of \$168,000, to the Health and Human Services Secretary for autism activities, and within that total, provides for three, distinct, autism-specific items. Sixteen and a half million dollars to the Centers for Disease Control and Prevention, to conduct the developmental disability surveillance and research program, which Dr. Gerberding outlined, the \$37 million for Health Resources and Services Administration to carry out an autism education, early detection, intervention program; and \$144 million for NIH-funded research.

Mr. Chairman, let me elaborate quickly on each of these. First, for the NIH, the funding increases are incremental, in total. Most

important, the act directs the NIH to spend those dollars more wisely, according to a strategic research plan, devised by an Inter-Agency Autism Coordinating Committee with consumers and advocates comprising a third of its membership. The act also directs the NIH to ramp up its investment in research, and potential environmental causes of autism.

With these new funds, CDC can expand its awareness and intervention activities, to reach more parents, health professionals, et cetera. Previous investment in the CDC has produced the largest-ever surveillance study, which established a baseline to measure autism prevalence trends in the United States.

These studies need to continue so that we can measure the true changes in autism prevalence over time. They probably aren't enough, by a long shot, but you know, that's the best we have right now.

It is also critical that funds be appropriated to the CDC to fund the Seed Study, which is the first epidemiological study to search for environmental exposure, and exposure gene immune interactions.

The Combating Autism Act also creates new and innovative State-based programs in autism education, detection, and early intervention. Early intervention, as we've heard here, can lead to improvements in speech relating to learning.

One of the things I would offer as a comment here, that—this is something we do know, that a child that does early intervention, is diagnosed before 3 years old, and is fortunate enough to have active therapy such as behavioral, occupational, or speech therapy, has a 50 percent chance of being able to matriculate to a public school. If you don't do that, you have almost no chance.

What we also know, is that children in the minority community, the average age of diagnosis is 7 years old. So, if you put those two together, there's almost no chance those children are going to be able to matriculate through a public school system. The two largest minorities are African-Americans and Hispanics, which total almost 80 million, in total. A third of our population is in the minority community. So, I mean, this whole thing, the cost involved, the issues involved, it's critically important.

Mr. Chairman, the funding increases recommended by the Combating Autism Act are relatively modest, at only \$25 million more than the Congressional Budget Office's baseline estimates for HHS's autism activities. But the impact this subcommittee would have by not just matching those increases, but by dictating how those funds would be spent, would be a start.

By doing so, Mr. Chairman, this subcommittee would take a giant step toward fulfilling the promise offered to hundreds of thousands of children and their families when Congress passed the Combating Autism Act. The public health crisis posed by autism requires an extraordinary response. With every new child diagnosed with autism, we're looking at another \$3 million bill over their lifetime—it isn't business-as-usual. I know you understand that, I know everybody sees this.

But we see a response needed that is akin to what happened with AIDS—a crisis in the 1990's. With line-item appropriations for autism intervention, surveillance and research tied to a strategic

plan. This is a leg-up, it's late-coming to recognize the prevalence, if we don't do something special, the funding won't rise at a fast enough level to deal with that.

I'm fully aware that the autism community is asking this subcommittee to do something which many claim to oppose, in principle, namely to appropriate by disease. In fact, Congress already took that extraordinary step when it passed the Combating Autism Act. The act—by authorizing the creation of autism-specific line-item appropriations—recognized that autism deserves, no, requires, this approach, because of the combination of autisms high prevalence, coupled with the historical neglect exemplified by the numbers you heard today on NIH and the inability to prioritize autism within its portfolio, at least at this juncture.

#### PREPARED STATEMENT

Last year, the House and the Senate unanimously passed the Combating Autism Act and we urge you to make the funding part of the implementation of the act, as it's written, equally bipartisan, and universally a supported effort.

Thank you very much, Mr. Chairman.

[The statement follows:]

#### PREPARED STATEMENT OF ROBERT C. WRIGHT

Good afternoon, Mr. Chairman. I am Bob Wright, chairman of the board of NBC/Universal and vice chairman of the board of the General Electric Company. But I appear before you today in another capacity, as co-founder of Autism Speaks and as a grandfather of child with autism.

Our grandson, Christian, was diagnosed with autism in 2004. Helpless, we watched him slip away into the cruel embrace of this disorder. My wife, Suzanne, likens it to a kidnapping, as if someone had taken away the life Christian was meant to live. We all want nothing more than to have him back where he belongs, restored to his family.

Since the diagnosis, our family has been on a mission to learn all we could about autism, and to help ensure our grandchild received the best therapy and treatments available. What we discovered, however, was just how scarce the resources are for parents dealing with autism, and how thin the knowledge. We had so many questions, and instead of answers, we confronted a bewildering array of theories and guesses.

Here's what we do know about autism.

—According to a recent CDC report, autism is now diagnosed in 1 in 150 children in the United States, and a shocking 1 in 94 boys.

—A decade ago, experts estimated the prevalence of autism to be 1 in 2,500.

—This year more children will be diagnosed with autism than with AIDS, diabetes and cancer combined.

—Autism costs society the American economy more than \$35 billion in direct and indirect expenses each year, according to a Harvard School of Public Health study. And caring for a child with autism can cost over \$3 million over the person's lifetime.

Frankly, Mr. Chairman, we were shocked that a disorder as prevalent as autism commands so little in terms of resources devoted to research and treatment, when compared to other, less common disorders.

—For example, leukemia affects 1 in 25,000 people but receives research funding of \$310 million per year;

—Pediatric AIDS affects 1 in 8,000 children; its funding, \$394 million per year; and

—Then there's autism, which affects 1 in 150 children and yet NIH research funding is a paltry \$108 million.

To help close this gap, we launched Autism Speaks in February 2005 to help raise the funds that will quicken the pace of research. Mr. Chairman, we also worked together with thousands of families affected by autism to introduce, pass and have the President sign the Combating Autism Act. This historic act is considered by some to be the most comprehensive piece of single-disease legislation ever passed

by the U.S. Congress. It authorizes appropriations of \$920 million over 5 years for autism research, surveillance, awareness and early identification, authorizing a 50 percent increase in the Department of Health and Human Service's spending on autism.

For fiscal 2008, the Combating Autism Act authorizes a total of \$168 million to the HHS Secretary for autism activities and within that total provides for three distinct autism-specific line items—

- \$16.5 million for the Centers for Disease Control and Prevention to conduct its Developmental Disabilities Surveillance and Research program;
- \$37 million for Health Resources and Services Administration to carry out an Autism Education, Early Detection, and Intervention program; and
- \$114.5 million for NIH-funded autism research.

Mr. Chairman, let me elaborate on each of these items.

For the NIH, the funding increases are incremental. Most important, the Act directs NIH to spend those dollars more wisely, according to a Strategic Research Plan devised by an Interagency Autism Coordinating Committee, with consumers and advocates comprising a third of its membership. The act also directs NIH to ramp up its investment in research into potential environmental causes of autism.

With these new funds CDC can expand its awareness and intervention activities, to reach new parents, health care professionals and health care providers. Previous investment in CDC has produced the largest-ever surveillance study which established a baseline to measure autism prevalence trends in the United States. These studies need to continue so that we can measure the true changes in autism prevalence over time. It is also critical that funds be appropriated to CDC to fully fund the SEED study, which is the first epidemiological study to search for environmental exposures and exposure-gene-immune interactions.

The Combating Autism Act also creates new and innovative state-based programs in autism education, detection and early intervention. Early intervention can lead to profound improvements in speech, relating and learning. Right now, we consider getting a diagnosis and intervention for a 3-year-old child a success. But we can do better. Through new diagnostic instruments we can reduce the age of diagnosis to within the first year of life. Service provision must keep pace.

Mr. Chairman, the funding increases recommended by the Combating Autism Act are relatively modest at only \$25 million more than the Congressional Budget Office's baseline estimates for HHS's autism activities. But the impact this subcommittee would have by not just matching those increases but dictating how those funds would be spent would be historic. And by doing so, Mr. Chairman, this subcommittee would take a giant step toward fulfilling the promise offered to hundreds of thousands of children and their families when Congress passed the Combating Autism Act.

The public health crisis posed by autism requires an extraordinary response. With every new child diagnosed with autism costing an estimated \$3 million over his or her lifetime, we cannot afford to rely on standard, "business as usual" practices. The autism crisis demands a focused, coordinated, and accountable response by our public health agencies, similar to the Federal response to the AIDS crisis in the 1990s, with line-item appropriations for autism intervention, surveillance and research tied to a strategic plan.

I am fully aware that the autism community is asking this subcommittee to do something which many claim to oppose in principal—namely, to appropriate by disease. In fact, Congress already took that extraordinary step when it passed the Combating Autism Act. That act, by authorizing the creation of autism-specific line-item appropriations, recognized that autism deserves, no, requires, this approach because of the combination of autism's high prevalence, coupled with historical neglect exemplified by the failure of the NIH to appropriately prioritize autism within its portfolio.

Last year, the House and the Senate unanimously passed the Combating Autism Act. We urge you to make funding the implementation of the CAA an equally bipartisan and universally supported effort.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much for your statement, and thank you for taking your time to be here today, and for all of your involvement in this issue.

Next, we'll turn to Mr. Bradley Whitford, well-known Broadway and TV actor, who is probably best-known for his role, of course, on "West Wing".

Mr. Whitford studied theater and English literature at Wesleyan University. Dr. Favell went to that school.

Dr. FAVELL. Illinois.

Mr. WHITFORD. Oh no, Connecticut.

Dr. FAVELL. He went to the other one.

Senator HARKIN. Different Wesleyan.

Dr. FAVELL. Yes.

Mr. WHITFORD. Different one.

Senator HARKIN. Oh. Where was yours?

Mr. WHITFORD. Connecticut.

Senator HARKIN. Oh, okay. Then earned a Master's Degree in Theater from the Julliard Theater Center, and again, Mr. Whitford, thank you very much for being here, and for your testimony, and please proceed.

**STATEMENT OF BRADLEY WHITFORD, VOLUNTEER SPOKESPERSON,  
AUTISM SPEAKS**

Mr. WHITFORD. Well, thank you, Senator Harkin, on behalf of the acting President of Autism Speaks, I want to thank you for your support on this issue.

Autism is not a disease that any beloved celebrity is going to come down with, and I know sometimes it seems as if celebrity has no place in discussions of priorities, but I hope you will forgive it, because these children have no voice, and it seems an appropriate use of the attention that actors get, to bring voice to them.

I came to this cause when my college roommate, movie producer John Shestack, and his wife, Portia Iverson, had their son, Dov, diagnosed with autism, and founded the amazing advocacy group, Cure Autism Now, which is known, lovingly, as CAN.

CAN recently merged with Autism Speaks, founded as you know, by Bob and Suzanne Wright, and I just want to take a moment to say, I know you're aware of the urgency here, but I want you to express to your colleagues the incredibly proactive nature of the autism community. It's the most heroic response to personal devastation that I have seen in John's family, to not only take of their family, but to reach out and help others. I know there is a great return on whatever investment is made in autism research and treatment.

Autism Speaks is going to make sure that all Americans, and certainly all of our elected officials understand the urgency of this problem.

As my friend, John, has said many times, it's as if 1 in 150 American children was being kidnapped. What would this Congress do if that was the case? What must it do to deal with these sad facts as they truly are?

I know the enormous burden of your high office means you must bear a certain stoicism. I also know that most Senators are parents, and grandparents.

Portia has written a book about Dov called Strange Son. Here's how she describes the kidnapping, "It was his mind they came for. They came to steal his mind. Before anyone gave it a name, even before I knew what it was, I knew it was in our house. They were very, very dark things, and there was no way to get rid of them. When I closed my eyes, I felt their shadows passing over me. I

didn't like to think about where they came from, or where they were going. It was too frightening.

Dov was only a baby, and something was trying to steal him away. I knew that that was what they did whenever I accidentally fell asleep. Night after night, I sat beside his crib. I knew he was slipping away from us, away from our world, and there was nothing I could do to stop it from happening, and there was nothing anybody could do, they told me. So, I did the only things I could—I guarded him. Although I knew it would do no good, because I could not guard his mind. Then, one day, it happened. He was gone.”

It is even more than just a tragedy for these kids, many of whom, like Dov, we now know to be of extraordinary intelligence, but trapped in bodies which do not allow them to effectively communicate or interact with the rest of us. It's also a tragedy for our families and for our country.

A mother of an autistic child recently told me, through her tears, that she had been forced to abandon her beloved life's work as a nurse, not mainly to give her more time with her autistic child, but rather to purposely make her family poor enough to qualify for the payment of some of the services her child so desperately needs. She said, “The one thing I won't do, even though I have friends who have, is get divorced just to qualify for additional benefits.”

Then there are the cases which don't make national news, but which echo loudly among people in the autistic community. About once a month, somewhere in America, the father of an autistic child kills the child, and himself, to end the despair.

Yet, despite all of this, there is some genuinely good news. The unanimous passage at the end of last year of the Combating Autism Act by both Houses of Congress can be an historic turning point. The act contains, for the first time, specific authorizations of appropriations to combat a single disease, including bio-medical research, public awareness, and consolidation and coordination of Federal efforts to ensure the early diagnosis of kids with autism, so they can get—when it matters most—the interventions that can give them the best possible quality of life.

#### PREPARED STATEMENT

Now the burden falls on you. I know you have many important matters before you. I also know that none is more important than this. In no other case do you have the opportunity and responsibility to fulfill the commitment made by this historic piece of legislation. These are our most vulnerable citizens. It is our obligation to make them realize their potential, and to make their voices heard.

Thank you.

[The statement follows:]

#### PREPARED STATEMENT OF BRADLEY WHITFORD

Chairman Harkin, ranking member Specter, members of the subcommittee—it's my great honor to be here today in the hope that my years of training as an actor and stomaching countless audition rejections have led me to some degree of celebrity which I can put to use, helping you garner the support you need to fully fund the appropriations authorized in the Combating Autism Act.

One in 10,000 kids will have autism. That's what top scientists would have told you little more than a decade ago. Then, it became clear that number was ridiculous. And the CDC—with the support of this subcommittee—started to really look at the prevalence of autism. 1 in 2,500, then 1 in 500. By the time the Children's Health Act of 2000 became law, the estimate had become 1 in 250. A few short years ago, the CDC said 1 in 166.

Now, just a couple of months ago, the best data ever collected produced the scariest number yet—1 in 150—1 out of 94 American boys.

I came to this cause when my college roommate, movie producer Jon Shestack and his wife, Portia Iverson, had their son, Dov, diagnosed with autism and founded the amazing advocacy group, Cure Autism Now, known lovingly as "CAN".

CAN recently merged with Autism Speaks, founded, as you know, by Bob and Suzanne Wright—on behalf of their grandson. Now this strong national organization is going to make sure that all Americans—and certainly all of our elected officials—understand the urgency of this problem.

As my friend Jon Shestack has said many times—it's as if 1 in 150 American children was being kidnapped. What would this Congress do if that was the case? What must it do to deal with these sad facts, as they truly are?

I know the enormous burden of your high offices means you must bring to bear a certain stoicism. I also know that most Senators are parents and grandparents. Portia has written a book about Dov—Strange Son. Here's how she describes the kidnapping.

"It was his mind they came for. They came to steal his mind.

Before anyone gave it a name. Even before I knew what it was, I knew it was in our house . . . They were very, very dark things. And there was no way to get rid of them . . . When I closed my eyes, I felt their shadows passing over me . . . I didn't like to think about where they came from or where they were going. It was too frightening. Dov was only a baby and something was trying to steal him away. I knew that was what they did whenever I accidentally fell asleep . . . Night after night, I sat beside his crib. I knew he was slipping away from us, away from our world. And there was nothing I could do to stop it from happening. And there was nothing anybody could do, they told me. So I did the only thing I could. I guarded him, although I knew it would do no good, because I could not guard his mind.

And then one day, it had happened. He was gone."

And it is even more than just a tragedy for these kids—many of whom, like Dov, we now know to be of extraordinary intelligence, but trapped in bodies which do not allow them to effectively communicate or interact with the rest of us. It's also a tragedy for families, and for our country.

I recently spoke to one mom who told me—through her tears—that she had been forced to abandon her beloved life's work as a nurse—not mainly to give her more time with her autistic child, but rather to purposely make her family poor enough to qualify for the payment of some of the services her child so desperately needs. She told me: "The one thing I just won't do—even though I have friends who have—is get divorced just to qualify for additional benefits."

Then there are the cases, which don't make national news but which echo loudly among people who "get it"—probably about once a month, somewhere in America—the father of an autistic child kills the child and himself, to end the despair.

Yet, despite all of this, there is some genuinely good news. The unanimous passage, at the end of last year, of the Combating Autism Act, by both Houses of Congress can be a historic turning point. The act contains, for the first time, specific authorizations of appropriations to combat a single disease—including biomedical research, public awareness and the consolidation and coordination of federal efforts to ensure the early diagnosis of kids with autism (so they can get, when it matters most, the interventions which can give them the best possible quality of life).

Now the burden falls on you, on this subcommittee, to turn Congress' promise on autism into reality.

I know how many important matters come before you. I also know none is more important than this. And in no other case, do you have the opportunity and responsibility to fulfill the commitment made in a historic piece of legislation.

I know you will do the right thing.

Thank you.

#### AUTISM AND THE ENVIRONMENT

Senator HARKIN. Mr. Whitford, thank you very much. You give a very powerful statement.



I thank you all very much, for taking the time to be here—as I said earlier—but also for your day in and day out efforts, on behalf of our families and our kids with autism.

I'll begin this round of questions now, and then yield to my friend from Illinois.

I want to start with our first panel, Dr. Insel, and I don't know if you're aware of this magazine article, the Discover magazine article that came out—maybe you are, maybe not—but I wrote down what you said in your testimony, you said that we must focus on this as a brain disorder. At least that's what I wrote down. I hope I can challenge you on that, and see what your response is.

This Discover magazine article had a map of Texas, and the top map was the autism rates per 10,000 from 1990 to 1993, up on top, you can't see it, but the bottom two are what's important. It was the autism rates per 10,000 of the last few years of the last decade, and then it had the pounds of environmental toxic release. When you overlay one over the other, it is frighteningly the same.

So, is there something in the environment? Why should we just focus on it as a brain disorder, but maybe it's, maybe there's something environmental out there, that we also ought to focus on, which is one question, and it leads to the second part of it—how much of the money, of the \$108 million that you invest in autism research, is on environmental aspects, looking at some of the environmental aspects of this?

Dr. INSEL. These are important questions, Senator Harkin, and the way that we think of this is that there is an environmental component, but it interacts with some genetic component. The reason we believe in the genetic piece of this, which is driving the brain pathology, is that there is such a high concordance in identical twins, it's difficult to explain that based on just an environmental factor, because in non-identical twins, the rate goes way, way down.

Senator HARKIN. Fraternal twins.

Dr. INSEL. Right. So, there's some effect—it's not 100 percent concordance, so there's something beyond genetics—so we're talking about both environment and the genes.

What are we doing about the environment? As you know, the 2007 budget that was approved by this committee involved an appropriation for the Gene Environment Initiative, GEI, that was a particular request from, in this case, the Secretary—not simply through NIH, but it was part of the Secretary's budget. This, you know, our Secretary Levitt came from EPA, and he came to Health and Human Services with a tremendous interest in environmental issues.

What he was recommending here was that we bring the very best genetics and the very best abilities on the environmental side together in this new initiative, and the \$40 million will be spent each year for 4 years. The first grants in that arena are just being funded in the next few months—

Senator HARKIN. Did you say \$40 million?

Dr. INSEL. Per year, for the next 4 years.

Senator HARKIN. On the environmental aspects?

Dr. INSEL. Not specifically for autism, but generally, if we're looking at gene-environment interactions—part of what's hung us up here—

Senator HARKIN. Through your Institute?

Dr. INSEL. This is the National Human Genome Research Institute doing the genetics part, and the National Institute of Environmental Health Sciences, which is developing the technology.

We have great precision on genetic sequencing, not such good precision on environmental exposure. So part of this will be to develop the tools, so that we'll have sensors, and other ways of looking at environmental exposures, often well after the fact.

Senator HARKIN. I still need to know, and if you don't have it right now, if you'd provide it for the record, about how much of that \$108 million goes in for environmental.

Dr. INSEL. We can provide that for the record.

[The information follows:]

#### ENVIRONMENTAL ROLE OF AUTISM RESEARCH

Of the \$108 million invested in autism research in fiscal year 2006, \$14 million was invested in environmental aspects of autism research by the following Institutes and Centers: NINDS, NICHD, NIEHS, NIMH, NCRR, and OD.

Senator HARKIN. Second, if we were to provide the increase that the groups have asked for, how would that money, that extra money be utilized in the next fiscal year? I'd like to have some handle on that.

Dr. Gerberding, I was shocked when my daughter and her husband showed me the schedule of vaccinations for my first grandchild in the first 2 years of his life. I was shocked. Evidently this is what is required; and they have good pediatricians, they go to great doctors out on the west coast, but I guess I just never realized that. I think, when my kids were born we had a couple, maybe three shots, but we didn't have this long list. I think 12 or 15, is that correct?

Mr. WRIGHT. Thirty-one.

Senator HARKIN. Thirty-one, thank you, Bob. Thirty-one.

Mr. WRIGHT. Zero to 18 months.

Senator HARKIN. Please, go ahead, what did you say?

Mr. WRIGHT. Between zero and 18 months, there are 31, including influenza.

Senator HARKIN. Okay. That's the list I looked up. They were upset, they were asking me, I said, "Well, I'm not a doctor, how do I know?" So, they wanted me to ask you.

I mean, I'm serious, they wanted me to ask. They're really concerned about this. About all of those vaccinations in the early ages. When you have a small child that's not an adult, I would be concerned if I had that many shots in 18 months. There has been, and there have been some, at least, allegations, some thought that perhaps, many of these, at least with the use of thimerosal, which was a mercury additive for preservatives, might have had some influence in that, although thimerosal has now been taken out.

Mr. WRIGHT. Not entirely.

Senator HARKIN. Except in the influenza, the influenza shot still has thimerosal, am I right?

Mr. WRIGHT. That's right.

Senator HARKIN. I think that's right.

Could you address yourself to that? Just the number of vaccinations, the fact that we still put thimerosal in the influenza shot, but it's been taken out of the measles, mumps and rubella, I understand.

Dr. GERBERDING. It's important, first of all, to recognize how many children are alive today because of those shots, and how little vaccine-preventable disease we see in this country as a consequence of the enormously successful immunization program.

Keep in mind that an immunization is really just a way to expose a child to a specific protein or antigen that causes it to develop an immune response, and that happens to children all of the time, naturally. They're exposed in their food, they're exposed to things they come in contact with their friends and with day care, so while they may receive intentional exposures to protect their health, they're naturally doing the same thing to themselves, just as part of being a child, and being exposed to the environment.

The concern about the safety of vaccine is something that we take very seriously at CDC, and we recognize that we're having our own challenges in keeping up monitoring the safety of vaccines when so many more are out there, and we haven't been able to scale our safety efforts the way we would like to.

But, we do know—and I think the scientists at the Institute of Medicine have provided great leadership in this, is that when all of the information that is available has been looked at by external scientists, not only has the Institute of Medicine said that vaccines are not associated with autism, but they have said that there is not an association, that there is no evidence for an association.

What we say to that is, that's good, and that's what we expected to see, but we have still a lot of work ahead of us to identify what are the safety aspects of vaccines, in general, but also what are the causes of autism? We need to continue the studies that we have in progress, including the study underway to look at the potential association of environmental toxins and autism, and the SEED study that's going on, and not be dogmatic.

I was really struck by Mr. Wright's statement about the similarity between autism and AIDS, because I lived through the very first phases of AIDS, and if you go back to 1981, the situation we were in with that urgent reality for many, many people in our country, is we had no idea what caused it, there was no cure, the people who were affected were driving the agenda because it was so powerfully affecting their lives and their health status, and the people that they loved and cared about. Government was slow to get on board, Government was slow to scale and provide the kind of scientific leadership, the door was open for junk science, and for all kinds of theories to come and go, and ultimately, it was the Congress of the United States that stepped in and provided the leadership and the investment to get that whole picture turned around.

Domestically, back in the eighties, and more recently, internationally with the PEPFAR fund. We don't want to go through that cycle again, and I think we really recognize that this is an urgent threat. While we're sitting here today in these 2 hours, at least six children will be diagnosed with autism in our country,

25,000 children this year. We really do need to regard this as an urgent threat. So, I just wanted to put that perspective in the context of your question.

#### AUTISM IN OTHER COUNTRIES

Senator HARKIN. Well, Dr. Gerberding, obviously, CDC during your epidemiological studies also, I'm wondering, are they also looking at some of these environmental factors?

Second, has CDC looked at autism rates in other countries? Has any research been done to see if countries in Europe and Asia have different autism prevalence rates? If so, can this tell us about possible environmental factors that can, or may contribute to autism?

Dr. GERBERDING. The SEED study that I mentioned that's going on in six sites initiated this summer is designed to look for a variety of potential associations and causes of autism, including exposure to mercury in the environment, in Rhogam, which is sometimes used to treat mothers with Rh factor incompatibilities, and a variety of other sources. So, it's looking at genes, it's looking at environment, it's looking at the social-behavioral context of the family.

Also looking at occupational exposures in parents that could potentially create a hazard of exposure in the home for children. So, a comprehensive look, as a first study.

You might know about the NIH study that will be starting in Europe in the cohort of Norwegian children—children in The Netherlands, excuse me—

Dr. INSEL. It's Norway.

Dr. GERBERDING. Norway—to follow a cohort of children longitudinally to look for prospective evidence of causality, and then there are studies, for example, in the United Kingdom, that have been tracking children over time, and looking at changes in rates.

Finally, a very important study that we don't have data from, going on in Italy, where just by coincidence, some children were enrolled in a study of a whooping cough vaccine, some of the vaccine was made with thimerosal as a preservative, and some of it was made without thimerosal as a preservative, so the study was designed to compare the efficacy of the two vaccines, we will indirectly be able to determine whether there's any difference in autism among the children who did or did not receive the vaccine that contained the preservative.

So, we have more information coming, but I think we're beginning to work in the international context of a community of investigators all looking for the same kinds of information. This is a global health issue, not just an American health issue.

Senator HARKIN. Well that's, that is comforting to know, that you—CDC is looking at other countries, you are coordinating with other countries to find out about the prevalence rates, and you're also looking at the Norway study, I know.

Are you also coordinating with Dr. Insel, and his Institute on this?

Dr. GERBERDING. The Norwegian study is an NIH study.

Dr. INSEL. But this is an area where there's a lot of coordination between all of these Federal agencies, we're actually organized around this. This is, very much, an integrated effort.

The Norwegian study, if I can just take a moment, because I think it's going to help us over the next couple of years. It makes no presumption about the cause, it says, "We don't know enough, to even have a hypothesis," but it takes 100,000 children, following them, their moms, from the second trimester to birth cohort, waits 5 years to see, 400 or so children with autism, and then it goes back, because samples are collected all the way from the very first prenatal visit. So, we have biological samples, we have a tremendous amount of clinical information. It goes back to ask, what is it, then, that might have been an exposure for the children who ultimately had autism, versus those who didn't?

Senator HARKIN. I'm going to yield to my colleague for some questions now, I have a couple more for Dr. Gerberding and Dr. Insel.

But really, in my next round of questions, I want to focus on you, Dr. Favell, and I want to talk about this intervention program which holds so much promise, and again, involve you and Ms. Colston in that, and also Mr. Wright, in terms of your experiences with your grandson, with Dov, and see how we start getting to families early on, and providing that kind of help and support, if we don't really have an infrastructure for it, and we don't—what's the most cost-effective way of doing it? I am intrigued by this idea of a tele-health distance-type thing where you could support someone in a family 24 hours a day, so I want to focus on that in my next round.

But, with that I would yield to my colleague from Illinois, Senator Durbin.

#### ALLOCATION FOR AUTISM

Senator DURBIN. Thank you, Mr. Chairman, and thank you to all of the witnesses. This is the first hearing I've attended on this issue. It isn't for lack of interest. There are many things pulling at us, in the position I have in the Senate, and the work that we have to do in so many other places, but I wanted to make a point of being here today. Not because we have any situation in my immediate family, that relates to autism spectrum disorder, but because of the number of friends that have been touched by this, and what appears to be the alarming increase in the diagnosis of autism across America.

My wife and I, fortunately, raised three children, and have a grandchild without a problem in that regard, but we frequently speak of this, the incidence of this, and why it appears to grow as it has, I know there's a serious question as to whether this is an indication of incidents or just identification now, better identification, but I think that begs the question. I think, the fact is, this is a significant challenge.

I thank all of you for testifying, Dr. Gerberding, again we really appreciate your public service, Dr. Insel, I'll have a question for you in a moment, thank you for what you do at NIH, and for all of you on the panel, starting with Ms. Colston and Dr. Favell.

Mr. Wright, you raised a question which comes to the office of a Congressman and Senator more frequently than you can imagine. People visit us from my State of Illinois or other places, and say to you, "Senator, can you possibly explain why they're spending 'x'"

amount of dollars at the NIH on this issue?” There are people who represent children with juvenile diabetes, there are people with parents who have Alzheimer’s, there are victims of Parkinson’s—you name it. They all come with the same basic question—how can they possibly rationalize this amount of money for this issue of such gravity, why isn’t more money being spent when it comes to research—and you raised that question. You compare the amount of money being spent on autism to other significant diseases and disorders, and I’d like to ask Dr. Insel the question.

Because, as I see the numbers here, in the past 10 years there’s been a dramatic increase at NIH in terms of research funding for autism spectrum disorders. In 1998, in the range of \$27 million, by the year 2008, about \$108 million, and I’d like to ask you, if you could, give me some indication of whether or not this amount is adequate to the task. Do you believe that you are able to fund the promising research proposals that come before NIH in the field of autism with this amount of money, \$108 million each year?

Dr. INSEL. Overall, what we call our success rate, that is the possibility that anyone in any area will get funded when they come to NIH is roughly 20 percent. There’s a 1 in 5 chance that you’re going to get funded.

Senator HARKIN. That’s a peer-reviewed.

Dr. INSEL. Peer-reviewed grant, that’s right. But, virtually all of our, other than contracts, virtually everything that we fund is through peer review. That’s a system that provides the quality control that we need.

Is autism—how does that stack up against other areas? Well, obviously, we’re doing better there, because it’s growing faster. Overall, the budget’s grown, a little more than double since 1997, this area has grown almost by five-fold, but remember, we were starting at a very, very low baseline. So, we still have a ways to go in this area.

I’m not proud to tell you that I can give you the full sum of our knowledge in less than 4 minutes, when we talk about autism. This is an area where we have many more questions than answers. We have a long way to go to fill in those answers. The good news is we have some of the tools now, that were not available 5 years ago. So, we should be able to make progress faster, going forward, than we have in this past period.

Senator DURBIN. So, does your response suggest that 4 out of 5 of these peer-reviewed clinical trials that you think are worthy of investment each year, have to be denied?

Dr. INSEL. Well, this isn’t to say that all of the other four would be worthy of investment. We would like to be able to fund, always, more than we can do, that’s the reality, it’s the same reality we all experience with our pocketbooks, we can’t go as far as we’d like.

However, in the area of autism, we’ve made that a priority, and we’ve tried to reach as far as we can.

The problem isn’t only that we may not have enough funding to do everything we’d like to do, but here also, we haven’t until recently, had the capacity, we haven’t had the population of outstanding scientists out there really pushing this agenda. That’s taken time to build. I think it’s there now, and I think part of it has been through the help that we’ve gotten from this sub-

committee, that's really helped us to grow overall, and it's also helped us to stay focused on areas of public health need, but there has to be the people out there asking the right questions for us to spend the money on.

Senator DURBIN. In order for those people to commit their lives and careers to that research, they have to feel that funding for research is somewhat reliable, and predictable in the years to come, is that not true?

Dr. INSEL. That is absolutely the case, and that is, of course, right now a particularly sensitive question. Because there are many people who are asking whether they can have a career in science, because they find that funding at this 20 percent success rate is a high-risk game.

Senator DURBIN. I think we made some dramatic progress, and I want to thank my colleague from Iowa and Senator Specter from Pennsylvania for all their leadership in that regard, but I'm afraid that we have reached a part where we're flat-lining stagnant here, in terms of the growth in medical research at NIH, and I hope we can change that. We are spending a lot of money in other places in the world, but I think most families would agree that this is a high priority for us to spend.

Mr. Whitford, you talk about, and I thank you, and Mr. Wright for being here, in your public capacities to engage in this issue—but you talk about the frustration of your friends, that you know, who find it difficult to qualify for help in Government programs without making some radical personal decisions about their finances and their marital status and things of that nature.

I think that is the part that Ms. Colston was raising earlier, too, is how do we sustain the families that are doing their level best to help their child, suffering from autism? I really believe that that is something that we overlook. Research is the first place to turn, but beyond that, it's support for these families with children in this circumstance.

One of the things that I've thought about is to view the role of caregivers in America as a special group that receive special consideration. Whether we're talking about daycare centers or personal attendants for the disabled, there is at least one State that gives all caregivers automatic health insurance, provided by the State. It's the State of Rhode Island, provides Medicaid for caregivers. It strikes me that in many instances, families with children with autism would be able better to afford the services of caregivers if they could offer health insurance as part of the bargain, and we can help them do that.

So, I'm hoping we can find some innovative ways to expand the spectrum of services for children who are going to need much more, but I thank you for raising that.

Mr. WHITFORD. I don't think it's possible to overstate the impact that I—actually my, I, subsequent to my involvement with CAN, my godson was diagnosed, and it was a different situation, they live in a one-bedroom apartment, they do not have the funds that they need, and it is absolutely devastating to a family, it is—depending on where you are in the spectrum, you know, these kids, it's 24 hours. There is a tremendous amount of anxiety wondering, where on the spectrum the kid will end up. There is, it's an abso-

lutely full-time job, the career goes out the window, the marriage goes out the window, and you're juggling therapies in a desperate race to see if your kid can live an independent life. So, it sounds like a great idea.

Senator DURBIN. I hope we can interest some people in it.

Ms. Colston, I'll ask you the last question I have, and turn it back to the chairman on this, but your son, Camden is in public schools now?

Mrs. COLSTON. He is, he's in Montgomery County, Maryland.

Senator DURBIN. How is that working out?

Mrs. COLSTON. It's great. I live—I'm lucky, again, I live in Montgomery County, Maryland which is the top 10 counties in the Nation in the way they handle disabilities, and the IDEA Act. It's great—he gets picked up at my door on the school bus, he goes to school, he gets 10 hours a week of intensive therapy, he is mainstreamed, or included if you will—not mainstreamed, he's included with his typical peers for a third of the day, and in a contained classroom for two-thirds of the day. I've seen just remarkable improvement in his socialization and cognition. So, I'm very grateful for that.

Senator DURBIN. Very fortunate to be in Montgomery County, Maryland.

Mrs. COLSTON. That's right, I'd say to people, "I love D.C., I'd love to move there, but I can't."

Senator DURBIN. That just tells the story.

Mrs. COLSTON. Yeah, right.

#### PREPARED STATEMENT

Senator DURBIN. A few miles away from you live——

Mrs. COLSTON. I can't move there.

Senator DURBIN [continuing]. The schools cannot provide the basic care that these children need. I think, I want to salute again my chairman, it sounds like I'm doing my best to get on his good side, but he had been a national leader on IDEA from the start——

Mrs. COLSTON. He has been, thank you.

Senator DURBIN. We're lucky to have him.

Thanks, Mr. Chairman.

[The statement follows:]

#### PREPARED STATEMENT OF SENATOR RICHARD J. DURBIN

As a United States Senator, I hear from thousands of people in my State of Illinois. But no stories are as powerful as those of a parent who is worried about their child. Whether the worry is because of the fear of having to pay for their child's upcoming educational debt, the angst of having their child abroad in a war that seems to have no end, or the uneasiness of having a child with autism and not knowing what the future holds for him or her.

As we have heard today, autism is a severe neurological disorder that affects language, cognition, emotional development, and the ability to relate and interact with others. Current estimates suggest that over 1 million Americans suffer from some form of autism, including more than 24,000 children in my State of Illinois. For unknown reasons, the number of children diagnosed with autism has skyrocketed in recent years, from one in 10,000 children born 10 years ago to approximately 1 in 150 children born today—making autism the fastest-growing developmental disability in our Nation.

Last year, I heard from a woman named Ellen whose story represents so well the similar sense of constant worry that I hear from so many others. Ellen wrote to let me know that her son's autism was a constant source of worry for her. She is a



mother that loves her son. At the same time, she worries that her son's siblings carry a genetic tendency and that their own hopes for marriage and children are tainted with concerns about how these genetic tendencies will manifest themselves in the lives of their own children. She worries that her other son one day will have to bear the strain of raising a child who is affected by autism. Ellen writes, "As much as we love our son, we would give anything to have him be 'typical'. He will always require supervision and assistance. He is the great passion of my life and also a very great burden."

My State of Illinois has seen a dramatic increase in the number of autism cases in the past 10 years. The number of children in Illinois receiving special education with autism as a primary diagnosis has grown from 1,960 to 9,455—more than a 450 percent increase. As more and more families become aware of the disorder and the impact on their lives, it is imperative that we all—federal, state, and local levels—make the most of our ability to promote research, advocacy, and policy for autism-related disorders.

The State of Illinois is very involved. Our communities are strongly committed. In 2003, the Illinois General Assembly passed a law to develop an innovative model of service delivery called the Autism Program to help these children and their families. Through a partnership with the CDC, this program offers evidence-based diagnoses, treatments, trainings, resources and referrals. Last year, the program provided more than 4,700 clinical contacts and trained more than 9,400 parents and providers. This year, there is hope to expand the initiative.

Late last year, the President signed into law the Combating Autism Act. The new law says we have authority to provide dramatic increases in federal funding for autism, specifically for medical research, screening tools, therapy interventions and education about the disorder. But the new law says something else, too.

Coupled with State based efforts like those in Illinois, the new law reflects the dawning awareness in Congress and throughout this country that far too many people are affected by autism spectrum disorder. It is my hope that this new law proves to be a significant step toward a better understanding of how to prevent autism, of effective treatments for people living with autism, and maybe even, one day, a cure.

The efforts conducted at the State and now at the Federal level will bring much needed action to address the growing prevalence of this disorder. More importantly, however, these efforts can bring hope to the thousands of families impacted by autism. We may have a long way to go but I look forward to today's discussion and learning what the CDC is doing and will do to help these families and keep such hope alive.

Senator HARKIN. Thank you very much, Senator Durbin. Thanks for your strong support.

Senator HARKIN. As I said, I wanted to get back to questions, I wanted to talk about interventions now, and how we handle, how to handle those now.

Now, Ms. Colston, tell me again, how old was Camden when he was first diagnosed?

Mrs. COLSTON. He was 2½ when he was diagnosed with autism.

Senator HARKIN. Two and a half, and you said that he'd made progress through intensive therapy, Individualized Education Plans, a sizable team of dedicated professionals. I mean, did that start right at 2½ when he was diagnosed?

Mrs. COLSTON. My experience was slightly different, as I mentioned. In addition to having autism, he's got medical ailments that he was born with, so when he was born, he was small for his age, he had horrible acid reflux—you've read the Discover article, so you're going to see a lot of parallels there.

Senator HARKIN. You read this too, then?

Mrs. COLSTON. In full disclosure, I not only read it, but I helped place it with Dr. Herbert, so—

Senator HARKIN. Bob Wright says he individually kept the magazine afloat for a month by buying up all the magazines.

Mrs. COLSTON. Thank you so much, Bob Wright.

Senator HARKIN. Sending them out.

Mr. WRIGHT. Largest single purchaser.

Mrs. COLSTON. It's a great thing. So, he was undiagnosed, but we had horrible acid reflux, we were hospitalized, we had these allergies, and they thought he had something called Noonan Syndrome, the diagnosis changed—all that being said, in the NICU these problems presented, and so therefore, the Georgetown University Hospital made me sign up for Early Intervention. I didn't even know what it was. So he, because he had low muscle tone and these other medical problems, at 6 weeks of age, the team came to my house. I know for a fact that he is where he is because they came to my house, and gave only 4 hours of therapy, but that, I mean, with them, he turned his neck, he sat up, he—they were the ones that actually—the therapists there are amazing, because they encouraged me to really look at the autism before the doctor saw it.

Senator HARKIN. Yeah, I guess what I'm wondering, and I—as I said I had dinner Sunday night, no secret, I had dinner with the former Lieutenant Governor of the State of Iowa, Sally Peterson, who's been very much involved in this issue. Their son, Ron is now, I think 20, 21, doing very well.

Mrs. COLSTON. Oh, good.

Senator HARKIN. But, again, they had early intervention, they could afford it, they had all of the accoutrements, everything that they needed. They asked the question—what happens to families that don't have the monetary resources that we do? How did you happen to—I don't mean to pry, but how is this—this costs money—

Mrs. COLSTON. Oh, oh yeah. I mean, my out-of-pocket annually—and I have good insurance, keep in mind.

Senator HARKIN. Yes.

Mrs. COLSTON. Is between \$9,000 and \$15,000 a year. That's not easy. At Autism Society of America, we have a 1-800-3AUTISM number, and it's a great resource, but we learned so much from that. Because the calls we get are about desperation financially.

Senator HARKIN. Sure.

Mrs. COLSTON. People—so, I'm lucky to be able to swing that, in good years and bad, but these people mortgage their homes—especially when their children become adults—that's where the rubber hits the road, financially.

Senator HARKIN. Now, this is where I'm going to focus on Dr. Favell. I am so intrigued by what you're doing. As many families tell me, or people I've talked to with autistic children, you know, when they go to the doctor's office, or when they see a behaviorist or a psychologist, maybe the child is not exhibiting anything at that time.

Dr. FAVELL. Right.

Senator HARKIN. When they need help is at home when things, go all to heck, all right? There's no one there. That's why I'm intrigued by what you're doing.

How, tell me, enlighten me a little bit more about how, how many families could a trained psychologist, behaviorist, someone who is trained and knows how to deal with children with autism, how many could they handle on some kind of a system like this?

I mean, on a 24-hour a day basis, I'm trying to figure, could one handle three families? Or two, or five? I just don't know.

Dr. FAVELL. Mr. Chairman, it's an excellent question, and the answer is just evolving, but for example, we did as part of our work with the Celeste Foundation, one demonstration that calculated that, if a professional, like a behavior specialist, was to provide in-home services, they might be able to visit two families a day, given travel distances, given missed appointments, given inclement weather, all of the vagaries of the logistics of supplying services, perhaps they could see two to three families a day. Of course, again, in more rural areas, that number decreases.

On the other hand, if you have a behavior specialist, or a behavior analyst, who is working with this interactive video kind of capacity, you could see potentially 20 families a day. Now, this kind of remote, this tele-health, does not replace face-to-face intervention and support, but it can augment it, and expand, exponentially, the number of families that can be touched a day.

Senator HARKIN. As I understand it, in the beginning you do have face-to-face involvement with the families, is that correct?

Dr. FAVELL. Yes, in the model that we tested in our demonstration project, they spent—the families such as Josh Cobbs' family—spend a week on-site, developing priorities and learning basic strategies of intervention and teaching. Then they went home with their interactive video system, and then that began the process of the interactive consultation, support and training.

It started with about 10 to 14 hours a week of interactive video support—it's a couple of hours a day. We think, actually, and the families tell us, it might be able to be somewhat less, it all is individualized, depending on the needs of the child. Then, it was after three weeks reduced to about 5 to 7 hours a week, and then 3 to 6 hours a week.

Senator HARKIN. I see.

Dr. FAVELL. So, there's yet to be worked out the formula for exactly the parameters for what is needed, and it will always be individualized, just as the IEP and the IHP requires, but the intuitive reasoning behind having one professional who now is able to touch lives through this remote medium is quite clear.

Senator HARKIN. What more do we need to do to test this out?

Dr. FAVELL. Well, I think we need to bring it, as we say, to scale. We need to test fully the economics of it, we need to test it across broader bands, including some other disabilities, and may I say, also, this kind of innovation should not be restricted to children alone. We can't forget the many, many thousands of people who are adolescents and adults who are adolescents and adults who are also living with autism. So, we have further to test there. But, I think probably the single most important element in bringing this to scale, as I say, is to develop the policies behind reimbursement strategies. If I, as a psychologist and a behavior analyst, can be reimbursed for providing services face-to-face in a home, than I should presumably, also be allowed to be reimbursed for providing comparable services, now, over remote interactive video. Yet, easily half of the States do not allow for that kind of reimbursement through Medicaid.

So, and then those States that do allow it, there's wide discrepancy in what they reimburse. Yes, sir.

Senator HARKIN. Let me ask you, Mrs. Colston. If you had had something like this available to you, would that have helped you?

Mrs. COLSTON. Yes, it would have helped me a lot. Not only because, most parents of children with autism work full time, and are probably hourly wage workers, and so getting off to run home for the times you can do an early intervention is tough.

But also, because then the therapist could see, as Dr. Favell says, the bad time of night.

Senator HARKIN. Yes.

Mrs. COLSTON. Where, when the behaviors of autism, it just gets harder to be a kid with autism.

Senator HARKIN. I'm, I have a note here, I'm holding in my hand that says Josh Cobbs is here, the father of Noah Cobbs who is in that news clip, is that right?

Mr. COBBS. Yeah.

Senator HARKIN. Oh, well Josh, welcome to the committee, I should have pulled up a chair for you and asked you a question. Yeah, come up here, come up here, sit down.

I didn't even know you were here. Now, the recorder is going to want to know your name.

#### STATEMENT OF JOSH COBBS

Mr. COBBS. It's Josh, last name is Cobbs, C-O-B-B-S. I am not prepared, but I'll do my best.

Senator HARKIN. I wasn't prepared to have you here, either.

But, I just want to know—now. We saw that little clip, obviously, you know, TV wants to get in the game, with all due respect to Mr. Wright, television tries to get it in a very short clip, tell me what this has meant for you and your wife and your son, on this, again, the availability of it, that you can do this during the day, right? On weekends, too, I don't know, can you, weekends?

Mr. COBBS. Sure, we actually had services, initially, 7 days a week, two calls, one in the morning, one in the evening, and we structured them around when we were struggling, such as sitting at the dinner table, or breakfast table, which was very helpful.

The doctors got to see Noah in his true element, so he wasn't acting up because there was a worker in the class, or in his, in our home, and he wasn't putting on, on-stage, if you will, so he was in his natural surroundings, which was very helpful for us, because that's where the behavior was happening. So, that was very important.

One thing I'd like to clarify, it's not just important for our immediate family, but also our, his grandparents, and aunts and uncles who are affected by autism as well, they were able to come in and help and once Tina and I were trained adequately through the Celeste Foundation and our immediate family, we then had the tools to go out and help others, so—

Senator HARKIN. Now, I'm told, I'll just throw this question out. I'm told that many times, what might be the normal reaction of a parent to a behavioral problem of a child, that if that child is autistic, it may in fact, exacerbate the problem, and make it worse, and so you have to have other approaches.

Mr. COBBS. Absolutely.

Senator HARKIN. I'm not a behavioral scientist, or anything like that, I've just been told that. So the answer is yes.

Mrs. COLSTON. We like to say that children with autism don't have osmosis, as many of us do. So, a lot of speech therapies and other therapies are talk, and so when you talk at a child, or even soothe them with your voice, you're changing the environment, and that may make them, there's a term called sensory violation—it may sort of freak them out a little bit.

For example, I was trying to comfort Camden, and I would stroke him—well that, that just makes him feel completely out of his element. So, there are things that a mother does naturally, that sometimes we have to alter, because children with autism like deep pressure, and that grounds them. Or vestibular inputs.

Senator HARKIN. So, something like a tele-health thing could be instructive in that, where you could actually talk to someone and say, don't do this, or do this?

Mrs. COLSTON. Right.

Mr. COBBS. Absolutely.

Senator HARKIN. Has that happened to you?

Mr. COBBS. Excuse me, absolutely. I do want to point out, the actual day that the TV station was there was Noah's worst day. Everything that could wrong, went wrong. He went outside, he was crying, he was kicking, it was—I was thinking to myself, "We are failing right now, as parents," with TV reporters there, and a few other people, and through the project from Celeste, they actually, right there, coached us through the moment, and it, it took about 40 minutes, to get Noah reeled back in, to get him back into the house, and to get him calmed down, but, wow, what a great feeling. That was a true test for us, is we can make that happen with the right help and coaching.

Senator HARKIN. Bob Wright, your grandson, how old is he now?

Mr. WRIGHT. He'll be 6 in August.

Senator HARKIN. Six. He was diagnosed early on?

Mr. WRIGHT. He was diagnosed at 2 years and 3 months.

Senator HARKIN. Now, his parents think about what we were just talking about, this is a new thing, here, about having that kind of tele-health, where someone could come into your home, so to speak, at any time of the day or night, would that have been of help to them?

Mr. WRIGHT. It's hard to say, I can't imagine it wouldn't have been helpful. My grandson has auto-immune problems, and he had gastro-intestinal issues which were not diagnosed at the time. So, they weren't diagnosed until 2 years later, almost 2 years. Which meant that he was suffering during that period of time, and we—nobody understood why. So, it was a very difficult situation with him. I think you made the comment, you're—in some respects a parent is better off, in some respects, if the autistic child has treatable, or at least has traditional medical problems. Because then you get access to doctors and hospitals and insurance. At least for some of it.

If you have no medical problems whatsoever, you don't get access to hospitals, doctors or insurance, really.

Senator HARKIN. Yes.

Mr. WRIGHT. So, if you, if you're awfully serious, on the other hand, and it's not diagnosed, you really are in a pickle. That's what my daughter found.

However, having said all of that, the kind of—anything that would allow a third party to be of help at the time, at the worst time of the day is going to be of benefit to an autistic family. There's no question about it—whether it's on the phone or whether it's in person, or—that is so important. Because the mothers just—I mean, you know, I worry as much about my daughter as I worry about my grandson. I worry about my daughter being on the edge all of the time.

Senator HARKIN. Yes.

Mr. WRIGHT. Because he has these serious problems, and he can't just—he can go from looking and acting very normal to get 104 degree temperature in like, it seems like, 3 hours later. You have to rush him right to the hospital. Of course, they look at him like, you know, "How could this happen?" They don't have a clue what he's, what's happening.

Turns out he has severe colitis, bordering on Crohn's disease, that's an adult, that's an adult condition, not a children's condition. You also find, though, in the case of a lot of these children, when they have medical problems, the medical protocols don't exist for children for some of these conditions. The medical protocols generally require the cooperation of the patient for diagnosis of certain kinds of things, like gastro. Where you can't talk to a child who can't talk. A child who won't express and react to—you point to your stomach, you don't point to his, he looks at you like, you know, you're from another land. So you, they don't, they can't be diagnosed in many cases, either, which makes it extraordinarily frustrating.

So, I would say that—I wrote down the Celeste Foundation, I thought that was an excellent concept, I'm not aware of it, and I think anything—I think one of the issues is how do organizations like that get funding? Do they, they have a foundation that gets them started, how do they get enough funding, so that they can begin to develop data, you know, that won't be sharply criticized by the first skeptical person that comes along.

Senator HARKIN. Yes.

Mr. WRIGHT. So that it can get, you know, it can get enough attention, it is very difficult to get insurance, it's very difficult to get State or Federal funds to support this, because the burden, the burden of proof is so substantial. So, that's a real challenge—how do you take this experiment and build it up and, you know, at some point, you run out of money to do that, and I think that's part of what Autism Speaks—we're trying to figure out how we can help groups like that when they get to a point, to get to the next stage.

Senator HARKIN. Because that's again, what I'm looking at, you said it was costing you \$9,000 to \$15,000 year, out of pocket.

Mrs. COLSTON. Yes, that's above and beyond—I mean, Camden's non-verbal, so of course, I've had 6.5 years of speech therapy—and it's always declined. So, that adds up, and medical issues and that. So, that's above and beyond co-pays.

Senator HARKIN. So, we do know. I'm going to make a statement, I don't know if it's scientifically sound or not, but everyone I've ever

talked to says that it is factual that, the earlier you get to a kid with autism, and you provide interventions and analysis, intervention, support, training, the proper kind of activities—that it can lead, later on, to them being more self-sufficient, more independent.

My friend Sally Peterson, and Jim Autry whose son Ron is now 21, lives by himself, has a job, takes the bus back and forth to work. They say, if it hadn't been for those early interventions it never would have happened. Because they know other people that didn't have that. Their kids, after 4 or 5 or 6, they just level out, and that's the end of it.

Mr. WRIGHT. Mr. Chairman, my grandson's costs are well over \$100,000 a year, out of pocket.

Senator HARKIN. Wow.

Mr. WRIGHT. Now, I can afford to help on that.

Senator HARKIN. Yes.

Mr. WRIGHT. But how many people could do that? That's why we're here.

Senator HARKIN. Well, this is what I'm trying to see, I'm trying to think of two things, here. How do we do more and better research, and I've got a couple of more questions I've got to ask you, too, and I know Dr. Gerberding has to leave. But then, how do we also do the most cost-effective, best methodologies to get the families that have kids now, so that we have that early intervention? I'm thinking that so many people out there can't get it, they may be isolated, they don't have the financial resources that some of us do, and if they don't have an attendant illness, they may not have anything.

So, if we can use something like a tele-health, a thing like that, where one trained person can interact with a number of families, and where families can get help when things go all to heck in the family, it seems to me that that just begs, begs for more expansion, to see how it would work, and to see if we can adapt this, adopt it, adapt it, adapt it to the, to a larger segment of our population. It seems to cry out for that kind of support.

Mrs. COLSTON. It seems to me, as a parent, that there's a natural fit. If you could take this technology, or your funding, and put it towards early intervention, which I think is IDEA Part C?

Senator HARKIN. Yes.

Mrs. COLSTON. You know, there are so many great models in place in this country, that are cost-effective, and that's one of them. And I wonder if you could marry those two through Part C, and see how it worked, or pilot it. Because I know that the early intervention therapists who helped me, they had a tremendously huge caseload. I think they got caught up in overall education funding as well.

Senator HARKIN. Yes.

Mrs. COLSTON. So.

#### TREATMENT RESEARCH

Senator HARKIN. I wanted to ask you a question, and I'm glad my panels are still here for Dr. Gerberding, Dr. Insel. In this party, in Discover magazine, there's some interesting, interesting language about different approaches to treating kids, people with au-

tism. There's some indication that using chelation therapy, chelation therapy, which I'm not all that familiar with, I just kind of halfway know what it is, after reading this, I looked it up some more, but that it quotes at least one or two families in here whose, I think they had more than one child that was autistic that went through this, and they just, improved immensely. I'm wondering, have you looked at that? Is there something there?

This, the doctor they quote in this is a Dr. Asco, she's a microbiologist, she has a Doctorate in Microbiology and other things. Now, I'm intrigued by this. Is this part of looking at, you know, of treating people with autism?

Dr. INSEL. One of the ways that, at NIH, we've tried to increase our effort in this whole area is to develop an intramural program, the first such program for focusing on autism. It started about a year ago, there are five protocols that have been rolled out there, and this is to have a kind of rapid response team that can pick up an idea and run with it quickly, where we don't have to go through a very long process of peer-review.

They have, as one of their protocols, they do have a chelation protocol, that was approved by our Science Committee in September. It's actually been held by the Institutional Review Board, whose members have some additional questions, they're going to address it again on May 1. So there have been no subjects actually entered into the protocol. But the hope is that will be approved and we can use this intramural program as the first place to do a controlled trial, a real, randomized controlled trial to find out whether there's, a, value in this approach, and b, what the risk is.

Senator HARKIN. Is NCCAM involved in that?

Dr. INSEL. I'm sorry.

Senator HARKIN. NCCAM?

Dr. INSEL. NCCAM is not involved. This is one that NIMH is taking the lead on.

Senator HARKIN. But, you say on May first, you're going to—

Dr. INSEL. May first the IRB, the Institutional Review Board, will be reviewing this particular protocol, and we are hopeful that once it's approved, we can begin to run with it. But I must say, they have has some considerable reservations, the Review Board itself, about the safety of chelation, they've brought in some outside experts who have made them even more concerned about the potential risks involved, based on some very recent animal research.

Senator HARKIN. Dana Halbutson, from Iowa, told me that chelation therapy made a big difference with her 8-year old daughter, Robin. So, again, this is something I don't understand completely, but if things are happening out there, that people are having success with, I would think that NIH would want to look at it.

Dr. INSEL. That's exactly why we have this intramural group put together for just that purpose, and it's not only on this, but on a number of other ideas that have come up, we're trying to move quickly to be able to test them out, but we want to bring the best science to those questions, and we want to make sure that we're doing it in a way that's safe as well as informative.

Senator HARKIN. I know, Dr. Gerberding, you have to go, and I'm respectful of your time, but again, I just, I want to be reassured that you're coordinating with NIH in your, in your epidemiological



studies, that you are coordinating with them, and that you're looking at, in your studies, the different aspects of these vaccinations that we talked about, I mean, look—I agree that, you know, the vaccinations obviously have saved a lot of lives. But, one has to begin to wonder, are there some other side effects that are happening out there that we don't know about? Maybe they need to be modified, or something, I don't know.

But, I'm just, I want to be reassured that CDC is coordinating with NIH, in looking at the possible causes, and maybe environmental factors that might, that might spur on the genetic predisposition to have autism.

Dr. GERBERDING. First of all, we are collaborating across the Department, in particular with NIH in two lanes that are relevant to your question. The first has to do with the autism agenda, and we have the inter-agency approach to doing that.

Separate from that, we have collaborative work going on, on vaccine safety, that includes NIH, CDC, FDA and the National Vaccine Program Office, and those are two separate but related issues, and we are fully engaged. I love to spend NIH's money. So, I have a very strong incentive to collaborate with NIH on the development and research agendas and so forth. I'm concerned, Senator, because I've been long aware of the worries about the safety of vaccine with respect to autism, but we really need to get past that, and I think one of the downsides of focusing on that association is that it's closed us off to really looking, broader, at some of the more biologically tenable hypotheses.

So, I want to reassure your daughter that she's doing the right thing for your grandchildren, but we also know that no vaccine is ever going to be 100 percent safe, and we have a responsibility to investigate safety, not just from this lane, but from the whole spectrum.

Senator HARKIN. I don't want to continue on this, we can discuss this at further hearings that we'll have, Dr. Gerberding. My point is not that these vaccines aren't safe. That's not my point. My point is, that you add them all up, and do we really know that 31 of those, given in the first 18 months—within that short span of time—each one of them may be individually fine, but do we know what the outcomes, what the impact is, say, on someone who may be genetically predisposed, to have autism. Then you hit them with 31 of these vaccines, all combated in a short period of time. What may be—how could that, perhaps, trigger that genetic predisposition? I don't know that you can answer that question.

Dr. GERBERDING. Well, I can tell you that it's not related to thimerosal. Because the childhood vaccines that your child, your children are getting do not contain thimerosal as a preservative, so—

Senator HARKIN. Except that one.

Dr. GERBERDING. If they, some of the flu shot vaccines still contain thimerosal, they're trying to take it out, but it hasn't happened—

Senator HARKIN. Yes.

Dr. GERBERDING [continuing]. Across the board, yet.

Senator HARKIN. Yes.

Dr. GERBERDING. But, it's a very small amount of thimerosal, and you know, we've been talking about, is the prevalence of au-

tism increasing in our country? It's continuing to either stay the same, or increase, even though we have removed the thimerosal as a preservative of vaccine for several years now, so——

Senator HARKIN. But I'm not talking about thimerosal. I'm just talking about the combined effects of all those vaccines on a small body that may be genetically predisposed anyway? That's what I'm talking about. I'm not talking about thimerosal.

Dr. GERBERDING. It's one of the hypotheses that, I think, needs to be evaluated in the studies that are going on. I don't think it's the most likely hypothesis, but it certainly should be included in the risk profile.

Dr. INSEL. I think the message that we'd like to convey is it's too early to reach premature closure on any of this—we simply don't know—I think all of us agree that there must be something beyond the genetics.

Senator HARKIN. There's got to be, because, Dr. Insel—and that's why I asked the question at the beginning—do we know what's happening in other countries? Now, there are other countries that have a pretty decent standard of living in which they do not give all of these vaccinations in the first year or two of life. Do we know what the incidents of autism is in those societies?

Dr. INSEL. We have good prevalence estimates for most of Western Europe and for Japan. So, we have some comparisons, and in fact, the United Kingdom is a good example where, in this case, the thimerosal came out in the early nineties——

Senator HARKIN. I'm not talking about, I'm just talking about all of those vaccines——

Dr. INSEL [continuing]. But in terms of the early child, and vaccines——

Senator HARKIN. Does every child in Great Britain get 31 vaccinations before they're 18 months?

Dr. INSEL. Julie would have a better idea of that.

Dr. GERBERDING. No, and their rate of prevalence of autism, if anything, is higher than it is here.

Senator HARKIN. Well, then I'd, that's what we'd like to look at. Other countries, too, to see what's happening. Now, that would be an interesting epidemiological study. To compare what we're doing here to other countries, and to see if there's any correlation. Now, you say they have a higher incidence in Great Britain than we have here.

Dr. GERBERDING. When we talk about the incidence or prevalence of autism, there's been an issue that hasn't come up in this hearing, and I just want to lay a marker down, so we can talk about it. In order to know how many children have this disease, we have to have access to their health records, as well as their education records. As you know, we are stymied in getting that information. So, in order to compare across countries, we have to be able to get similar information from all of the other countries that are in play here, and that's really touch—that's a tough challenge to make those direct comparisons.

Senator HARKIN. You had, earlier, a memorandum of understanding with the Department of Education.

Dr. GERBERDING. That's right.

Senator HARKIN. I understand that they stopped that because of privacy concerns.

Dr. GERBERDING. Well, smart people have looked at the law, the Family Education Responsibility Privacy Act, and the Department of Education attorneys have interpreted that law, to say that our means of having access to children's educational records is inconsistent with FERPA, that act.

We think, our responsibility is toward the HIPPA Act, the Privacy Act, and under the Privacy Act, public health utilization of data is allowed, so there's a stalemate here, and the Department of Health and the Department of Education are trying to work this out, but right now, it's really jeopardizing our ability to understand the true prevalence of autism in our children, and that's a big concern to me.

Mr. WRIGHT. We've looked at this at Autism Speaks, this is a very serious issue, because it, obviously so much work has been done at Government expense at CDC to put in the system of developing the data that the CDC is publishing, and this whole system relies upon getting information from school records. If you lose that, the system—which has taken several years to build—will collapse, and it would be a lost, you know, tons of—years will be lost.

My personal conclusion is, that having looked at this, hard, that it probably is going to take, it is going to take some congressional action to clarify this. Because it, after all, it is going to end up being the reading of legislation and when you have disagreements, you're going to have different kinds of positions, and at some point or other, I think, that's going to require a congressional, a few lines, in a few bills, to say that this is the interpretation we intended. Because this all comes from congressional legislation over prior years. It probably is absolutely necessary.

Senator HARKIN. Well, I would welcome any suggestions you have that your, or your organization has on legislative changes, legislation that we need to do to change the language so that we can get that kind of information from the Department of Education.

Mr. WRIGHT. We would be happy to help you in any way we can.

Senator HARKIN. I would appreciate that—that could be very, very helpful. Or you, or anybody else. I don't know if I could call on Federal Government people to do that, or not, I don't know if I can ask you to do that.

Well, listen, this has been a very helpful hearing. Again, I feel good that through NIH that we're doing more research.

Now, we have ramped it up, but I do want to say this. I hear every time, I hear people tell me, "Well, you know, the percentage increase has been so great here or there." I always remind people that from zero to one is infinite increase.

Now, I've got to know where you start before you tell me what the percentage increase is. I want to look at the total dollars, and what is needed and what can be used. That's why I ask, Dr. Insel, if we had this increase, could it be used, what it would be used for, and whether or not.

Now, I do believe that your answer to the questions of Senator Durbine, I think informs me that, yes, if only 20 percent of the peer-reviewed are being funded, well, that indicates that, obviously, there are more out there that can be funded, that are peer-re-

viewed, obviously. So, that we can provide that kind of, if we provide that funding for you.

But, I also thank the other panelists for being here. I, we've just got to do something about getting to these kids earlier. Darn it, we just always patch and fix and then later on it costs us a thousand times more. If we can get these kids earlier with the kinds of interventions that we know works. I mean, we've seen what's happened with families that had the wherewithal to do that and we've seen what's happened to their kids and how much better they perform. So, what's most cost effective? How do we reach out?

I am anxious to see how the Celeste Foundation will expand this and we'd like to be helpful in any way we can. But, I just, my senses tell me that this could really be very helpful to a lot of families around the country who are somewhat isolated. I'm thinking of rural areas, obviously in small towns and communities where they just don't have the ability to get that kind of intervention.

So, I'm hopeful that we can take a further look at that. I would, I would invite any from you, Dr. Favell, any suggestions that you have for how we might expand the scope of this. You suggested that in your testimony in response to a question.

Mr. Whitford, I just want to say that, that you mentioned something about celebrity status. I wrote it down here, about celebrity. You know, people pay attention to people like you and, you know, if you're one of those celebrities that are dancing with the stars, or running off to the Riviera and all that, well, people read this, they pay attention. But, if you're a celebrity and you're using your status, and the fact that you reach a lot of people and you're using that to focus people's attention on good things that they can do to help our society, to help people live better, to help us do our job here—I think that's commendable. I just want to commend you for that, for doing that, and being out in front on this issue. It helps a great deal that you would use your status to do that and I appreciate it very much.

Do we have anything else that any of you want to say for the record or, anything before I call this to a close, at all?

Dr. Insel?

Dr. INSEL. I think all of us would like to thank you for your interest in this problem. This is the first such hearing we've had on this topic and for everyone here at the panel, even for somebody who's not at the panel, but right behind us. This is a mission, and we really appreciate your interest and your willingness to support it.

Senator HARKIN. Well, I appreciate all of you, and the organizations that you started or that you've been involved in. Dr. Gerberding, I thank you for your great leadership and Dr. Insel.

Mr. Whitford, no Ms. Favell.

Dr. FAVELL. Yes.

Senator HARKIN. Dr. Favell, and all of you.

So, this, I think, this is the first hearing of this nature, but there will be more. I'm hoping that our budget, again to echo what Senator Specter said at the very beginning, I just hope that within our budget confines that we can move ahead more aggressively on this whole area of autism than we ever have before. It, it almost is like that AIDS epidemic. We've just got to get to it.

Mr. WRIGHT. Mr. Chairman, this reminds me, almost a little bit, of the early 1980s. There were two things going on. It was the AIDS issue was going on and, if you also remember at that point in time, there was this enormous outcry for cancer treatment, effective cancer treatments. People were running off to South America and Mexico and France. It was not like one or two people. It was, that they were just going down there for treatments, they were all considered to be too risky—

Senator HARKIN. Yes.

Mr. WRIGHT [continuing]. For the United States. That brought on a tremendous surge in, in cancer study. Some of it had to do with AIDS, some of it didn't. You had, Herceptin came out of all of that and you had the AIDS vaccine and the AIDS treatment. You know, it took a period of time, but it was an enormous upswing.

I get, I have a sense that this is the same, we're in the same timeframe here with the same kinds of issues.

You know, even though Dr. Insel is, I understand exactly the concerns of safety, but there are thousands of children that are undergoing that Kelation, one or more of those Kelation processes today. The parents are all told, they all know there are risks involved. They're saying, "Look at the risks I have at home. I have to make a judgment. Look at the state of my child. If this has a possibility of making him better, much better, I'm going to have to take the chance. Because I just don't, I don't believe I can't."

So, there is, there is a, it isn't going to Mexico for cancer treatment, but it is going, this Kelation activity, you know, rightly or wrongly, is a little bit like that migration that took place, you know, years and years ago.

#### ADDITIONAL STATEMENTS FOR THE RECORD

Senator HARKIN. Well, I hope and trust that we'll be looking at that and that NIH will be examining that. I hope this May 1 IRB will come through and it will be moving ahead on that, in that area of research.

[The statements follow:]

#### PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, thank you for scheduling this hearing to discuss autism and the spectrum of disorders related to autism. Since the month of April has been designated by the Senate as "National Autism Awareness Month," it is fitting that we have a discussion on this important issue during this time. We welcome Dr. Gerberding and Dr. Insel as members of the panel today. As leaders of Federal agencies tasked with autism surveillance, research, and treatment, your insight into current programs and your vision of future efforts to combat this disorder is important. We appreciate other distinguished panel members joining us today to provide their unique perspectives of the impact of autism disorders. We look forward to your comments and your direction on how this committee can be helpful in addressing your concerns as we move through the appropriations process.

Autism Spectrum Disorders are developmental disorders which affect a child's social interaction, behavior, and basic ability to communicate with others. The prevalence of autism-related disorders continues to increase, with recent Centers for Disease Control and Prevention reports estimating that 1 in 150 children in our country is affected, referring to this increase as a national public health crisis. Despite the increased attention to autism in recent years, the cause remains unknown and a cure is not available.

Congress has been responsive to this heightened public awareness and focus on autism from the medical community. The Combating Autism Act of 2006, which I cosponsored in the last Congress, was signed into law in December. This comprehen-

sive legislation authorizes approximately \$800 million over the next 5 years for research, early detection and intervention of autism. For the upcoming fiscal year, the President's budget contains no new funding for the Combating Autism Act and recommends level funding, approximately \$115 million, for existing autism programs at the CDC and the NIH. Autism advocates have requested an increase in this funding to \$168 million to expand autism efforts.

I look forward to your comments on the status of the current programs and on how an increase in autism funding would be used.

---

PREPARED STATEMENT OF ALLISON CHAPMAN

To Whom It May Concern: I am a parent of a child who regressed into Autism after his vaccinations. I have several areas I would like addressed at these hearings and I hope that an A-CHAMP representative will be there to represent my son and the hundreds of thousands of others with the same story. The following are a list of my questions,

- Will there be money for double blind studies using the DAN! (defeat autism now) protocol?
- Is there an understanding that Autism is a Whole Body Illness which can be treated?
- Will there be a vaccinated vs. non-vaccinated study?
- Will there be monies for studies on the dangers and implications of thimerosal (49.6 percent ethyl mercury) like the Burbaker study?
- Will there be an extension to these genetic studies to find out if it is Mercury (a known mutagen) that is causing deletions and mutations in the DNA?
- WILL THERE BE BIOLOGICAL TESTS TO FIND OUT WHAT'S GOING ON IN THESE KIDS BODIES THAT MIGHT BE CAUSING THE BRAIN DIFFERENCES?
- Will there be monies to teach Drs and pediatricians that Autism can have many medical issues that need treatment and to refer them to professionals who understand this like DAN's, Toxicologists, GIs, etc.
- Will you separate vaccine safety into a separate, independent organization other than the CDC which is the org that mandates them (A tremendous conflict of interest)?

I my mind there are 4 areas of Autism that need attention. Diagnosis, Educational intervention, whole body medical treatments that are already helping these children and research broken into BOTH environmental and genetic pieces. I've seen much in the areas of diagnosis, education, and genetics but by concentrating on those only leaves the biggest areas untouched. This is about the children and making them better or else the windfall of financial assistance it will take to support these kids who don't get treatment for the rest of their life, will most likely bankrupt this country. Thank you so much for your time. I truly do look forward to what happens in this Senate hearing, I am hoping you side with the children no matter what.

---

PREPARED STATEMENT OF ANNA W. WOLK

I am the very proud mother of a young man diagnosed with PDD/NOS-high functioning Autism at the age of 3. Adam is now 14—nearly 15—and as puberty has set in, so have many new behaviors. He has become frustrated with an inability to express his anxiety over the many changes occurring within his body, and as a result has become aggressive with us, his parents. What has become increasingly clear to me as we travel our journey that is autism is three things:

(1) We all (as parents of any child) have the same destination in mind—we are simply traveling different routes to get there,

(2) There are many books and tons of advice for the parents and families of newly diagnosed children, but nothing of substance for those of us who have made it to the teen years,

(3) The State of Illinois is not servicing our children as well as the rest of the Nation. Why is it that, when my son turns 20 years 364 days old, he is cut loose from the system. Is it the State of Illinois' opinion that, on my son's 21st birthday he is magically cured? If only it were true!

It is a disgrace that we are ranked 48th out of the 50 States in services for our Special Needs children and their families—and we must include the families, as Autism affects the entire family unit.

Luckily, my husband and I have not become one of the many couple who have divorced due to the pressures of raising a child with autism, but I can tell you the

toll—both emotional as well as financial—is a huge burden. And the effect on the siblings is enormous as well, as they don't get to have a normal childhood either. Simple things like birthday parties, sleep overs or even extra-curricular sports require enormous analyzing before undertaking them. Many times, the siblings just have to forego many of the usual rites of childhood because of their siblings needs.

When it is time to plan for the disabled child's future, there is no central "clearinghouse" of information regarding residential settings, day programs, vocational training, etc. It's purely luck of the draw and word of mouth. Many times, it comes down to who you know.

Well, I don't know anyone. I don't have any idea where to begin this new phase of my son's life, and there's no direction from the school system. I feel lost to my son, and I feel lost as to how to help him.

ANYTHING you can do to help centralize information for parent's and families would be an enormous help.

Current statistics reveal that 1 in every 150 children is diagnosed with Autism—one of them is my son.

Help create a miracle—support Autism Research and Awareness.

Thank you for your time.

---

#### PREPARED STATEMENT OF THE NATIONAL AUTISM ASSOCIATION

On behalf of the Board of Directors and membership of the National Autism Association and SafeMinds, we thank Senator Harkin and all the committee members for holding these hearings to ensure funding the Combating Autism Act. Once fully funded, this landmark legislation will help answer questions of vital concern to the autism community: what causes this disorder, now at epidemic levels, affecting 1 in 150 children, and how can it be most effectively treated and prevented.

Several dozen recently published peer-reviewed scientific papers point to environmental triggers, including vaccines and their components, as a cause of autism. Most recently, a study by the Autism Genome Consortium Project of 1,500 families with multiple affected children failed to identify an autism gene and failed to replicate most highly touted finding from recent genome scans. The negative AGPC findings provide strong evidence that heritability claims are exaggerated, if not false. Provided with massive resource support and under the most favorable study conditions, the AGPC found no evidence of heritability. These powerful findings suggest that the search for the actual cause of autism must focus on the environment to which the mother, fetus, and infant are exposed.

In the report language accompanying the CAA, Congressman Joe Barton stated, "... the legislation rightfully calls for renewed efforts to study all possible causes of autism—including vaccines and other environmental causes." Representative Barton also said, "... these provisions will insure continuation and intensification of crucial research at NIEHS so that it is able to conduct all necessary research to determine the environmental factors in autism."

Senator Chris Dodd stated in the Senate colloquy, "In our search for the cause of this growing developmental disability, we should close no doors on promising avenues of research. Through the Combating Autism Act, all biomedical research opportunities on ASD can be pursued, and they include environmental research examining potential links between vaccines, vaccine components and ASD."

With acknowledgement from our Federal Government that environmental factors such as mercury from vaccines may play a role in the development of autism, and a clear directive that this will be investigated by the National Institutes of Environmental Health Sciences (NIEHS), the National Institute of Mental Health, and other Institutes, we must now ensure that this area receives the necessary funding to establish a solid program of goal-driven research.

Rather than merely counting the children diagnosed with autism, we now have government confirmation that autism is a national health emergency that must be addressed with all deliberate speed. The government can move quickly and decisively when it wants to. Recent examples include the coordinated responses to E. Coli outbreaks in spinach, SARS, and threats from bird flu and mad cow.

Autistic children deserve and must have this same level of commitment and response. Imagine how quickly the government, indeed every institution of society, would react if 1 in 150 children were suddenly kidnapped. This is the stark reality faced every day by families with autistic children. Autism imposes massive costs to families and society, totaling \$3.2 million in lifetime care per individual, according to a recent study from Harvard University.

Epidemiology studies performed by the CDC must now test a clear environmental hypothesis rather than simply count affected children. Also, since it is scientifically

impossible to have a genetic epidemic, the funds spent on finding an “autism gene” should more appropriately be devoted to finding the environmental triggers. NIEHS must play a leading role as such research is within its area of specialization, while NIMH and other Institutes are best equipped to fund research within their areas of expertise.

Placing the major focus of government research on the environmental factors triggering autism and on biomedical treatments reaffirms the National Autism Association’s long-standing position that there is hope for all families affected by autism. An environmentally triggered disorder is both treatable and preventable; therefore, there is hope—hope both for families that already suffer with autism and hope that this disorder can quickly be relegated from an epidemic to the annals of history.

To that end, we urge this committee to fully appropriate the Combating Autism Act. In the area of environmental research including vaccines and their components, we ask the committee to include a line item amount of \$45 million over 5 years, as was authorized in the Senate-passed version of the bill. These funds should be specifically designated to the NIEHS so that this under-funded area of research can finally receive the attention it deserves. Hundreds of thousands of children suffering with autism spectrum disorders, that we now know is caused by one or more environmental factors, are depending on the wisdom of this committee to fully fund this critical research directive.

---

PREPARED STATEMENT OF ROBERT J. KRAKOW, ESQ. PRESIDENT, A-CHAMP

My name is Robert J. Krakow. Thank you for this opportunity to submit written testimony regarding the epidemic of autism and neurodevelopmental disorders that exists among our children. The autism epidemic is the most urgent public health issue facing our Nation.

This testimony is submitted on behalf of A-CHAMP, a political action organization that is comprised of thousands of parents nationwide. We have supporters in every state and District Leaders in more than 200 Congressional Districts. Most of our members have evidence showing that their children, labeled with autism, are vaccine injured, heavy metal toxic, with proof that their children are mercury-toxic. Notwithstanding this focus we advocate for all children with autism, irrespective of the possible causes of their disorders. We are a 100 percent volunteer organization that is organized on a grassroots and “netroots” basis. We are all parents or grandparents trying to improve the welfare of our children.

We appreciate the opportunity to submit written testimony and to have an A-CHAMP representative make a statement in person before the committee. As you know, we learned of this hearing only two business days prior to the hearing. We have had many members of A-CHAMP contacting their Senators and the committee to impress upon you our right and desire as stakeholders on this issue to voice our concerns about the autism epidemic and about our children. As a preliminary matter we wish to express our concern that only one organization appears to have participated in the planning of this hearing and to have been invited to testify before the committee, other than representatives of the Centers for Disease Control and the National Institute of Mental Health. We do recognize that once you heard our concerns about this hearing the subcommittee was responsive to our concerns and offered the opportunity to submit our concerns in writing.

It was A-CHAMP that alerted the larger autism community about this hearing and urged other organizations that are concerned with autism to attend, participate and submit testimony. This reflects a core principle of A-CHAMP that our government must recognize that there are many stakeholders that have claim to a voice on the issues affecting children with autism and that, notwithstanding the claims of one organization, it is not the case that a particular organization speaks for all of us. I think you have learned from our telephone calls and other communications over the last several days that no one but A-CHAMP speaks for us or our children.

I also wish to emphasize that our organization represents many constituents of the honorable members of this subcommittee. I have conferred with residents of Iowa, the home of this committee’s Honorable Chairman, Tom Harkin, and they have authorized me specifically to state that this submitted statement reflects their views and concerns. These individuals include among others Dana Halvorson, Lin Wessels, John Olsen, Ruby Olsen, Meg Oberreuter, Barb Romkema and many others. Similarly, in Pennsylvania, home of the ranking minority member of this committee, Senator Arlen Specter, Holly Bortfeld, and Colleen Strom, among many others have authorized us specifically to represent their views to the committee. This is but a tiny portion of the parents we represent in every State of the Union.



The issue of which persons or what organization is the authentic voice of our children is one that is not easily answered, despite the claims that you may hear. We appreciate the responsiveness of this committee to our concerns in this regard.

I am the father of a 7 year-old boy named Alexander who became sick in 2001 at the age of 2 years old, after receiving flu shots that were recommended by the Centers for Disease Control. An immunologist and pediatrician first diagnosed him with heavy metal toxicity, immune dysfunction, colitis, hypotonia, endocrine dysfunction, multiple additional autoimmune symptoms and a list of other physiological disorders too long to state here. My wife and I were told to immediately see a neurologist. We later brought our son to a world-renowned neurologist who observed a child who was very ill, in great pain but who had nothing to offer but the label of autism.

My son is unable to speak but is an extremely intelligent and loving child who is very related to his parents and sister. My daughter is 13 years old and is in Middle School and loves her brother dearly.

I am an attorney. I spent the first decade of my career as a prosecutor in Manhattan serving for 5 years as a Bureau Chief with the Office of the Special Narcotics Prosecutor for the City of New York. I have been engaged in the private practice of law for 18 years.

I became involved in working for individuals with developmental disabilities before my son became ill. I have served as chairman of the board of Lifespire, Inc. for 5 years. As you will read in separately submitted testimony, Lifespire is a large 55 year-old not-for profit with 1,500 employees that serves 6,000 developmentally disabled persons every day—in group homes, day centers, supported work, medical clinics, after-school programs, transition counseling and many other areas. Lifespire, formerly Association for Children with Retarded Development (“ACRMD”) has always served individuals with autism. In the last 5 years we have devoted a great deal of time and resources to developing programs for children and adults with autism. Lifespire was founded by parents and its Board consists today primarily of parents or relatives of individuals with developmental disabilities. We are a home-grown, local, community-based organization, even if we have grown large over the years. The reason we grown large is because we and others have advocated long and hard over the past half-century to improve services for the developmentally disabled. In our State of New York the response has been good in some areas. In other parts of the nation the response has been uneven. Lifespire’s concern is not research or etiology. Our concern is client-centered individually tailored community-based services and supports.

Now we need to confront a new emerging challenge—a very real increase in the numbers of individuals, mostly children aged 4–17 who are diagnosed with autism.

At Lifespire we knew very well in 2002 that there was an unacceptably high number of cases of autism among children, that rates of autism were 1 in 150 or higher and that there existed then, in 2002, a looming crisis for our State. We also knew that the prevalence of autism was something new, because for 50 years we were in the business of serving individuals with disabilities. While autism was always present in some of the population who we serve, it was not nearly as prevalent among our adult population as what we were observing among children.

In 2002 we knew that we needed to act immediately to address the crisis in services that would result as the leading edge of children with autism—the cohort of increased prevalence born around the year 1990—moved forward in age. Sadly, little has been done in the last 5 years by government to address these concerns.

Lifespire provides services and does it well for a long time. The tradition of Lifespire was born in a crucible of parent activism that became necessary because the schools and government were not responding the needs of families. 50 years ago parents joined together to provide for their children, by pressuring government to do what was necessary. 30 years ago ACRMD /Lifespire parents blew whistles outside legislators’ windows to call attention to problems with our care for those who area least able to care for and speak for themselves—then they were whistleblowing about infamous Willowbrook and the institutional abuse of disabled children.

As I stated, Lifespire’s CEO will be submitting testimony separately.

Sadly, today, things are better but children and adults with developmental disabilities still suffer abuse and often do not get the care that they need.

It is evident from the overwhelming response to this hearing today that parents are once again active. Two years ago, along with some dedicated parents we founded a national political advocacy group called A-CHAMP, and I am honored to serve as its President. We have 10,000 supporters and we are growing. Our volunteer parent-advocates throughout the country have already persuaded legislators in many States to enact provisions to make vaccines safer, thus protecting children, and to make insurance coverage fairer for individuals with autism.

I have a message for you as legislators. Parents are mobilized. We do not need nor do we use professional lobbyists. We find our children's interests are best served by direct parent-citizen communication with legislators. We find that professional lobbyists who may be employed by some large organizations do not necessarily understand what our children need. Parents understand what our children need and we are sufficiently sophisticated, motivated and organized to make sure that our children's voices are heard loud and clear, so that our children's needs may be heard, even though many cannot speak.

We urge you to get it right on this—get it right on the autism issue. The parents know what's right and they will be heard.

I call for what we describe as "A Culture of Advocacy for a Lifetime of Care." Around the State and the country parents are learning to advocate for their children. This echoes the story of Lifespire. My uncle and cofounder of Lifespire was a postal worker who, 60 years ago, had a child with special needs. He was also a labor organizer. In those days there was nothing for children like my cousin, Eugene. He and a few other parents created an organization and changed the laws of New York State by direct parent advocacy, not through professional lobbying. His campaign was called "A Children's Mandate." My uncle is gone now for some 10 years but his son has a home and an extended family to watch over him at Lifespire—for LIFE. My uncle gave him the greatest legacy—a lifetime of care by people who care. His mandate for his son and many other children was realized.

Nothing will stop the advocacy of a parent who fights for his or her child. At A-CHAMP we have worked hard to empower parents around the country by instilling them with the will and desire to advocate for their children so that they will be taken care of with love and generosity. When a parent fights for his own child he or she fights for every child.

I say to you as legislators that this is the problem confronting you—how to use limited resources to create a lifetime of care for our children. Parents expect a lot from our government—you—and our children deserve it. These hundreds of thousands of children will be the responsibility of our government. We need to come to grips with the problem and we need to do that NOW.

We are years too late and we are playing catch-up—we are playing with the lives of children.

I would like to address a few specific areas that are of great concern to me and many parents that address the subject of today's hearing.

#### COMMUNITY CONTROL OF SERVICES AND RESOURCES

We have developed detailed information on the daunting costs of caring for an individual with autism through his or her lifetime. We know that for an autistic adult the cost of care from age 23 through 66 will be approximately \$17 million for an individual who is severely disabled and at least \$10 million for an individual who is less severely disabled. These numbers are based on actual experience and are explained in testimony given by Mark Van Voorst, CEO of Lifespire at a March 8, 2007 hearing conducted by the New York legislature. I have attached a copy of Mr. Van Voorst's testimony. Given the Centers for Disease Control's recent estimate that there are exist 560,000 children under age 21 with autism, and probably many more given the reports of 1 in 94 children in New Jersey having some form of autistic spectrum disorder the costs of caring for our children will be staggering. We know from hard and concrete experience that the costs will be in the trillions.

We are already many years late in addressing the demands that this crisis will make on our resources. We will need innovative ideas in housing, in creating bridges to our communities for our developmentally disabled adults, and in providing therapeutic and loving environments for our children. Most importantly, we must create an environment in which parents will feel confident that as they grow old their children will be provided and cared for—"A culture of advocacy for a lifetime of care."

What does this mean? It means that when we develop a "coordinated response" to addressing the autism epidemic we must understand that we are dealing with individuals and not numbers. This means that we must direct our resources to solutions that are community-based. We see in legislation pending before this committee and laws already enacted that one approach to the autism epidemic is to create large centralized institutions that will address needs on a mass scale. While a massive response to the autism epidemic is required that response must not be overly centralized and it cannot favor one or a few gatekeeper organizations that aim to control the autism industry. We must invest in local and regional institutions so that we may build a community of care. We must involve parents in homegrown organizations because only then will our precious children receive the care and con-

cern that they deserve. I fear that the solutions to services and support issues that have been promoted before Congress, including the Combating Autism Act, do not reflect these values. I have observed that moneyed power organizations driven by a corporate model have gained access to Congress by professional lobbyists and have begun to dominate the public forum on autism. For the sake of our children this trend must stop.

I have spoken with many parents around the county, including those in Iowa and Pennsylvania, among many others. They have told me that what works for their children are integrated community-based programs that address their needs and provide supports where they live. This builds community and provides service. They require a combination of behavioral approaches applied locally in community centers or at home by qualified therapists, in combination with approaches that address the fundamental physiological disorders that have caused our children to become ill. I will address the issue of using effective non-pharmaceutical biomedical interventions for our children later in this statement, but the important point here is to provide services and supports through community-based parent-driven regional and local organizations. Our experience is that these organizations are usually most effective if they are structured on a not-for-profit rather than a for-profit basis. Profit making ventures certainly may have a role in providing services but they should not be the gatekeepers or primary caregivers of our children.

I would like to address another point that has arisen in the context of this hearing. One witness invited to this hearing will address a strict behavioral approach to therapy for children with autism that focuses on delivery of service by interactive video—a method dubbed “telehealth” that involves, in part, installing a video camera in one’s home and engaging in therapeutic sessions by video. It appears that the Department of Education and the NIMH have devoted substantial funds to research in this area. I have studied this area over the last few days and consulted with many parents about it. The universal response to this approach to service delivery is surprise and rejection. Children with autism are often characterized by their inability to develop proper socialization. They cannot speak—they need social reinforcement. It is incongruous to think that therapists in remote locations who essentially “phone it in” can address these problems and others.

We urge you to invest in our communities and not some technological fix that can lay claim to addressing children with needs when in reality it presents a method of providing services on the cheap. While I welcome learning more about telehealth I have serious concerns about this approach toward providing therapy for our dear children.

#### RESEARCH

Autism is not genetic. A recent genetic research study that cost more than \$10 million found almost no clear indication of a genetic association with autism. At most, the researchers found genes that might create susceptibility to environmental toxins, but their great breakthrough was finding a gene association in 1 out of 1,168 families. The researchers will dispute what I have said here, but quietly other researchers will tell you I am correct. There is no “autism gene.” We can produce well-respected researchers to support our position.

Epidemics cannot be genetic because gene mutations occur very slowly. The unavoidable evidence points to an environmental factor or trigger that has caused the upsurge in the numbers of cases of autism. Yet, little government or private research money is devoted to the study of environmental factors.

For reasons that are not valid, research in autism has been disproportionately devoted to genetic research. Notwithstanding the bias by private organizations and government to fund genetic research a great deal of peer-reviewed replicated research has shown that autism is a physiological disorder. The emerging research research strongly implicates environmental toxins and toxins from vaccines, including mercury, in creating impairment leading to physiological disease.

We must have honest research that inquires into every area of autism etiology regardless of who may find the results of such research inconvenient.

Parents supporting A-CHAMP almost universally believe that vaccines have injured their children, either alone or in combination with other external toxins to which their children have been exposed. We have also found that treatment focused on addressing these problems have worked to improve the health of many children and even recovered some children fully from autism. Our children’s physiological disorders are not comorbid or unrelated to their autism. Their physiological disorders collectively are what autism is—and result in the observable behavioral symptoms that we define as autism. We need research into these treatments—re-

search that has shamefully been ignored or set aside because it is too controversial. Backing off from controversy will not help our children.

Some valiant practitioners from the Autism Research Institute, DAN!, Thoughtful House in Texas and others have developed effective treatments and undertaken vital research that is directly helping our children today. Why is this research ignored or actively suppressed by our government agencies? How can “evidence-based” treatments such as these be validated if there exists no funding for the supporting research? The answer, of course, is that it cannot be validated. A highly manipulated scenario has developed that has resulted in a self-fulfilling prophecy: condemn treatments as “anecdotal” and not sufficiently evidence-based while simultaneously blocking funds necessary for research that will validate the same treatments. We regard this process as a cruel and unacceptable joke that has deprived our children of the chance for recovery. The scenario is not acceptable and our parents will work tirelessly to change it.

Recently, we were pleased to learn that the NIMH had initiated a chelation study. Without going into detail we were concerned about the study protocol used for this study because we knew that the protocol did not reflect the methods many of us have used successfully in chelating our children, safely and effectively. We have also heard rumors that this study has been suspended. We urge the committee to investigate why research like the chelation study is not proceeding and further, make sure that practitioners who have used chelation successfully are consulted in constructing meaningful research protocols.

There are some questions raised by some about whether there is a true increase in the incidence of autism among our children. We have observed some so-called experts in the field revise past estimates of prevalence of 1 in 2,000 children affected in the 1980’s as being incorrect because current research shows a rate of 1 in 150 or higher. We hear claims that current methods result in better counting and that autism at current rates have always been with us but that individuals with autism were “hiding in plain sight.” We reject such claims as the product of an agenda promoted by those who need to deny the existence of an epidemic to protect the vaccine program or avoid potential liability for vaccine related injuries.

So that we may know with certainty how many children and adults are affected we need epidemiological studies conducted by independent researchers outside the CDC or the government. We also need a study comparing individuals who are vaccinated versus those who are unvaccinated to determine which group has more disease. Legislation calling for such a study was introduced last session and will be introduced again. We support it.

Finally, the CDC has placed barriers to access to by independent researchers to the Vaccine Safety Datalink (“VSD”). This database can help answer questions about the cause or causes of the autism epidemic. The Institute of Medicine has severely criticized the CDC’s handling of the VSD. A panel of public and private experts has found that productive research can be conducted using the VSD to answer the question of whether vaccines or their components cause autism, a question not yet fully answered using the VSD. Yet to shield the VSD from outside researchers the CDC has paid a private company millions of dollars to house the data—data developed by the investment of millions of dollars of taxpayer funds. We respectfully request the Senate to conduct an investigation of this issue.

An addendum is attached to this statement that contains a non-exhaustive list of areas of research that we believe have been ignored and require attention.

#### TREATMENT

There is great controversy over treatment for autism, as discussed earlier in a different context. While Applied Behavioral Analysis (“ABA”) has helped some children it is not the panacea that some originally thought it would be. Yet, at every turn the only treatment option offered by medical professionals and schools is ABA. The use in legislation of the words “evidence-based” to validate treatments will surely result in the only approved treatment covered by insurance to be ABA.

I can tell you that my son has made tremendous progress not because of some strict regimen of ABA—the technique has been used to some extent with him—but through the use of various non-pharmaceutical biomedical interventions. My son’s so-called “tantrums” were the result of one thing: severe gastrointestinal inflammation. He was in pain.

Once this was treated my son was able to become the happy—very related to his family—child he was meant to be. It is a myth that children with autism are all in their own world and cannot relate to others. It is also a myth that little can be done to improve their condition and welfare. Much can be done; we have done it. I know other parents are submitting to the subcommittee information about bio-

medical intervention that can effectively treat autism—a physiological, neurobiological disorder. I have met many children who have completely recovered by children through non-pharmaceutical biomedical intervention. Yet, few research dollars are devoted to this area. Those who criticize biomedical interventions in autism decry the lack of “peer-reviewed” research supporting “evidence-based” research. This criticism is a self-fulfilling prophecy made by those who block the very research that could support diets such as the specific carbohydrate diet, supplements such as methyl B12, hyperbaric oxygen therapy, safe methods of chelation therapy and many more.

At the same time pharmaceutical treatments such as Prozac, Ritalin, Concerta, Adderall, Zyprexa, Seroquel, Geodon and others are used even though they are untested and unapproved for children, and have serious side effects. While Risperdal has been approved for treatment of irritability in autism it gained approval only through the expenditure of large sums of research dollars, and it is most definitely not a treatment for autism. It too has serious side effects that its manufacturer failed to disclose until the manufacturers were pressured to do so.

While there may be place for pharmaceuticals in some cases focus on these non-treatments have sucked the life out of any effort to produce research that will satisfy those who seek peer-reviewed research. Notwithstanding this, the research has been produced, often privately. More needs to be done.

#### INTERAGENCY AUTISM COORDINATING COMMITTEE (“IACC”)

The Combating Autism Act did expand the Interagency Autism Coordinating Committee. But the IACC was not given sufficient authority to conduct oversight over the NIH research agenda. In addition, for too long the community participants in the IACC have been limited to the same individuals from the same organizations. The IACC has been ineffective. The key to making government responsive to the autism crisis is to listen to the parents. They know what their children need. Give parents a central role in fashioning government’s response to the autism crisis. Broaden the participation in the IACC to voices outside the ones that bureaucrats may find safe. The IACC and other government/private committees should not be window-dressing that allows government to make empty claims that the community participated in their decision-making on policy. Community and stakeholder participation must be genuine so that members of our community can say that their voices are being heard. Many in our community believe that they are excluded from the process and that the IACC and other committees are not functioning, as they should in a democratic society.

Returning to the theme that introduced by testimony I want to emphasize that our government must give all parents, not just those from one or two self-selected groups, a central role in solving the autism epidemic. If government fails in this area the consequence will be a public health, political and social problem even greater than the one we face today. A-CHAMP’s slogan is “We Are Everywhere, and We’re Not Going Away.” We are watching our government’s response to the autism epidemic with great attention because our responsibility to our children’s welfare and future mandates such scrutiny.

Parents are mobilized, engaged, empowered. We are sophisticated and smart. We are also beleaguered and our resources are strained to the breaking point. We urgently need help now for our kids. We are ready for government to become our partners in addressing the autism crisis—but that means true partners in our communities, not public-private partnerships with special interest group organizations.

On behalf of all the supporters of A-CHAMP I thank you for convening this hearing today to listen to our concerns. We appreciate the opportunity to be heard. Given that this testimony was prepared on extremely short notice I will be happy to answer any questions from the Committee to clarify or amplify the points I have made in this statement.

#### ADDENDUM

##### SUGGESTIONS FOR SOME AREAS OF RESEARCH ON AUTISM

With respect to research we recommend the inclusion of the following areas into a research agenda on autism and environmental factors:

- Research related to treatment of autism as a “treatable” or “reversible” condition. Specifically, the focus must be placed on autism as a chronic impairment, resulting from oxidative stress. For example, there exists evidence showing that autism is characterized by the presence of “sick” neurons rather than “dead” ones or even impaired development processes (e.g., GABAergic neuron migration). This type of research highlights the inherent reversibility of the disorder

and must be pursued with urgency in order to develop and validate treatment of the disorder.

- Research on large cohorts of children to determine their status based on testing for urinary porphyrins, urinary toxic metals, urinary amino acids, organic acid tests, immune panels, cytokine testing, chemokine testing, etc.
- Research of the use in treatment of autism of anti-inflammatory medications such as Actos, Celebrex or Singulaire in quelling inflammation in the gut and brain and in reducing levels of pro-inflammatory cytokines and chemokines;
- Genetic research should be focused on single nucleotide polymorphisms and their relationship to metabolic and other mechanisms that create vulnerability to environmental toxins (including vaccines) rather than the latest genetic research focusing on genetic anomalies or CNV's that have not been tied to a biological mechanism affecting more than a tiny number of children;
- Research evaluating the mitochondrial status of children diagnosed with autism. Mitochondrial impairment plays such a strong role in MS;
- Full investigation of the role of heavy metals, including mercury, aluminum, lead and arsenic, from any source, in any form (including thimerosal), specifically including vaccine exposures in the etiology of autism;
- Complete access to the Vaccine Safety Datalink data by independent researchers outside the government;
- A recognition in developing a research agenda that vaccine sourced exposures may be a contributing factor in many cases of autism alone or in conjunction with other environmental exposures;
- Funding of research of the biological mechanisms that may contribute to autism;
- Full investigation of the role of viruses, bacteria and other infectious agents independently or in conjunction with other environmental exposures in the etiology of autism;
- Research of environmental factors, including the MMR vaccine, as they relate to gastrointestinal symptoms and histopathological findings” and treatment of these underlying bowel problems;
- Investigation of the effect of various metals, viruses, toxins with each other and other environmental agents—also known as synergistic toxicity—in the etiology of autism;
- Research of the role urinary porphyrin profile analysis can play in measuring heavy metal toxicity;
- Research of the role of mercury and other toxicants in ambient air pollution, including toxicants emitted from coal burning power plants, in the etiology of autism;
- A thorough analysis of the role of thimerosal, heavy metals, and other toxins play as mutagens and how this mutagenicity may play a role in autism;
- The role of the hypothalamus-pituitary-adrenal axis in the etiology and treatment of autism.

---

PREPARED STATEMENT OF MARK VAN VOORST, CEO/PRESIDENT OF LIFESPIRE

Good morning/good afternoon. My name is Mark van Voorst. I am not a physician, scientist, geneticist, statistician, nor even a practicing clinician so my comments will not address the issue of the rise in the numbers of individuals diagnosed with autism, nor will I attempt to offer any insights regarding the cause of this phenomenon.

However, for the past 29 years I have worked as an administrator in organizations that provide an array of services to individuals diagnosed with Mental Retardation or other forms of Developmental Disability. I am presently the CEO of a large not-for-profit organization in New York City which provides services to roughly 5,000 individuals per day and my comments are intended to enlighten the Committees on the enormous challenges that every New York State voluntary agency will face in the coming years as we struggle to ensure that all children and adults who are diagnosed with an Autism Spectrum Disorder receive the supports and services they will need.

In February 2007, the Center for Disease Control and Prevention released a new finding that concluded that the rate of autism in the United States is now 1 per 150 births. The National Census for 2004 shows that there were 4,115,590 births in 2004. Using CDC's figures, this means that of all of the children born in 2004, roughly 27,437 will be diagnosed with some level of autism. Current national estimates suggest that there are already between 560,000 and 800,000 individuals who are diagnosed with some level of autism.

In 2003 the New York State Office of Mental Retardation and Developmental Disabilities estimated that there were 52,991 individuals with autism.

In 2004 the National Census figures for New York indicated that there were 250,894 births. Using the newly released CDC figures, this means that roughly 1,673 of all new births in 2004 will at some point be diagnosed with autism. Current literature suggests that roughly 50 percent (45 percent—60 percent) of these 1,673 individuals will also be diagnosed with an IQ of 70 or less, which means that in addition to being autistic, they will carry a diagnosis of Mental Retardation. It is safe to say that of the 1,673 children born in 2004 who will be diagnosed with autism, approximately 837 will require some level of support and assistance throughout their entire lives.

As I am not an educator, I do not know the cost of providing supports and services to these individuals from birth to 21. However, I can give you some idea of what it will cost to provide support and services to these individuals once they become adults. The figures I am presenting are based on real, current annual costs for providing day and residential services at Lifespire Inc.

*Individual with a high level of need*

Day Services—\$44,174  
Residential Services—\$154,764  
Combined Annual Costs—\$198,983

*Individual with a lower level of need*

Day Services—\$26,686  
Residential Services—\$109,489  
Combined Annual Costs—\$136,175

If we now project these figures over the lifetime of an individual who needs ongoing supports and services (between the ages of 23 and 66 = 43 years) and build in an annual increase of costs of 3 percent the total costs rise dramatically.

*Individual with a high level of need between 23–66*

Day Services—\$3,933,615  
Residential Services—\$13,790,753  
Cost over 43 Years—\$17,724,368

*Individual with a lower level of need between 23–66*

Day Services—\$2,376,328  
Residential Services—\$9,756,402  
Cost over 43 Years—\$12,132,730

Looking only at the 837 children born in 2004 who may well need lifelong supports and services, it will cost between \$10,155,095,010 (low side) and \$14,835,296,016 (high side) to provide services once they leave the school system.

In 2003 the Office of Mental Retardation and Developmental Disabilities estimates that there are 52,911 individuals with autism currently in New York. Until we have an actual breakdown of the ages of these individuals we have no way of knowing how many are currently being served and how many are about to enter the adult service world. However, I think it is fair to say that the need for increased funding will be staggering.

CRISIS NUMBER TWO: WHO WILL PROVIDE THE SUPPORTS AND SERVICES?

In January 2006 the U.S. Department of Health and Human Services released a report entitled “The Supply of Direct Support Professionals” (DSP). HHS estimated that, in 2003, approximately 874,000 individuals worked full time providing care for roughly 4.3 million Americans of all ages. Most importantly the report noted “DSPs are essential to the quality of life, health and safety of more than one million Americans who are in need of long term services and supports”.

By 2020 the demand for DSPs will grow to 1.2 million. This represents an increase of 37 percent. However, during this same time period the available pool of labor will increase by only 7 percent.

HHS also estimates that on a national level there is a 10–11 percent vacancy rate in all Direct Support Professional positions. The situation is so severe that many existing service providers are refusing to expand services to meet the growing demand because they cannot recruit and retain the work force necessary to do so. Additionally, the turnover rate of DSPs is estimated to be 50 percent nationally.

While perhaps not as severe as the “national problem”, Lifespire Inc. is experiencing both crises identified in the 2006 HHS report. At any given time we have between 80–100 positions that are not filled and our turnover rate for those individuals providing direct support to our consumers in 2006 was 39 percent. While I have

not seen any figures for all of New York State, I suspect that my experience at Lifespire is shared by most, if not all not-for-profit organizations in the State.

The legislature and OMRDD have done a wonderful job providing resources that enable organizations like Lifespire to serve New Yorkers with developmental disabilities. Unfortunately, the funds allocated by the legislature are still not enough to allow us to attract and retain a skilled work force. Unless we are in a position to both attract new staff while at the same time are given the dollars to retain our existing staff, the wave of individuals diagnosed with autism which will begin to spill over into the supports and services within the "adult world" will simply overwhelm the provider system and will have disastrous consequences for an entire generation of children and their families.

During one of his campaign speeches, Governor Spitzer stated that it was important that we "take care of those who cannot take care of themselves", and that "everyone who has special needs will get the care they need for as long as they need it".

Mr. Chairman, I believe that we have a moral obligation to ensure that all New Yorkers who have been or will be diagnosed with autism have access to a service system that is both sufficient in size and sufficiently well trained to provide the services and supports that they will need. While I certainly hope that there is funding for ongoing research to determine a cause for autism, I also implore the Committees to take this message back to the full Senate and Assembly so that increased dollars flow to the voluntary provider community or to parents so that they can directly purchase the services they feel their children need. If we do not do something soon the provider community will simply not be equipped to deal with the numbers of individuals diagnosed with autism who will need adult services.

#### ADDITIONAL COMMITTEE QUESTIONS

SENATOR HARKIN. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

#### QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUE

##### AUTISM SPECTRUM DISORDER

*Question.* I would like to thank the Centers for Disease Control and Prevention (CDC) for their attention to accurate reporting of autism spectrum disorders by each State. The startling rise in the prevalence of autism spectrum disorders presents many challenges to society. The uniqueness of Hawaii raises even further challenges when one considers the remoteness and relative lack of resources available to support individuals affected by autism spectrum disorders. How can the Centers for Disease Control and Prevention (CDC) work with States such as Hawaii with rural areas and other unique needs to contribute to a better understanding of autism spectrum disorders?

*Answer.* Early identification and intervention hold the most promise for children and families affected by autism spectrum disorders (ASD) and other developmental disabilities. CDC is working with partners on a campaign reaching parents, health professionals, and childcare providers with information on developmental milestones and the early signs of autism. The campaign—*Learn the Signs. Act Early.*—is helping to change perceptions about the importance of identifying developmental concerns early.

Recent ASD surveillance data show concerns had been raised for more than half of the children with autism or related disorders prior to their third birthday, yet children were not diagnosed until well into their fourth or fifth years. Encouraging early intervention will help children reach their full potential during the critical window of early development.

Since the launch of the campaign in October 2004, information about *Learn the Signs. Act Early.* has been made available to more than 11 million health care professionals, parents, partners, campaign champions, and child care providers. CDC and its partners have distributed more than 83,000 resource kits targeting the three major audiences.

CDC continues to work with campaign partners on new ways to reach parents, child care professionals, and health care providers with the most up to date information about developmental disabilities—including ASD. Also, CDC has been working



with partners to reach underserved populations—including minorities and both urban and rural/remote populations. For example, campaign staff recently worked with the Autism Society of America (ASA) on a project to increase dissemination of campaign materials in underserved communities (including rural populations) through ASA chapters throughout the country.

The campaign is also in the process of piloting multi-disciplinary teams of medical professionals, educators, policymakers, and parents to develop action plans to address obstacles in early identification and intervention at the State and local level. If this model proves to be successful, it could be replicated in additional States.

#### COMBATING AUTISM ACT

*Question.* A recent study by the Centers for Disease Control and Prevention (CDC) found that autism spectrum disorders now affect 1 in 150 children in the United States, up more than tenfold from a decade ago. The Congress responded to this growing public health crisis when it passed the Combating Autism Act, which authorized more than \$900 million over 5 years for the Department of Health and Human Services' autism activities. How does the NIH and the National Institute of Mental Health intend to implement the Combating Autism Act's recommendations with the budget recommendations that have been sent to us?

*Answer.* The NIH has made considerable progress in implementing provisions of the Combating Autism Act (CAA) of 2006 (Public Law 109–416). A noteworthy accomplishment was the creation of the Autism Centers of Excellence (ACE) program, which received \$25.5 million in fiscal year 2007. The ACE program represents a consolidation of two existing programs, the Studies to Advance Autism Research and Treatment (STAART) and the Collaborative Programs of Excellence in Autism (CPEA), to maximize coordination and cohesion of NIH-sponsored ASD research efforts. The ACE program encompasses research centers and networks focusing on a broad range of autism-related research, including topics such as neuroimaging, biomarkers and susceptibility genes, pharmacotherapy, early intervention, and personal and environmental risk and protective factors.

#### INTERAGENCY AUTISM COORDINATING COMMITTEE

*Question.* How does the National Institute of Mental Health intend to implement the recommendations of the Combating Autism Act with respect to the Interagency Autism Coordinating Committee (IACC) strategic plan?

*Answer.* The Combating Autism Act (CAA) of 2006 (Public Law 109–416) requires the Secretary of the Department of Health and Human Services (HHS) to establish a new Interagency Autism Coordinating Committee (IACC) with the following responsibilities regarding autism spectrum disorders (ASD):

- Develop and annually update a summary of advances in ASD research
- Monitor Federal activities with respect to ASD
- Make recommendations to the Secretary regarding any appropriate changes to Federal activities and public participation in decisions relating to ASD
- Develop, annually update, and submit to Congress a strategic plan for the conduct of, and support for, ASD research, including proposed budgetary requirements

The IACC was chartered under the Federal Advisory Committee Act (FACA) with the National Institute of Mental Health designated as the lead for this activity. With a sense of urgency and a spirit of collaboration, the IACC is developing a strategic plan for ASD research that focuses on the unique needs of individuals with ASD and their families. The plan will encourage public and private partners to work together to rapidly advance our scientific understanding of ASD, improve health and well-being across the lifespan, and help individuals with an ASD lead fulfilling lives. In developing the strategic plan, the IACC assembled expert workgroups to tackle challenging tasks, identified recent investments and accomplishments in ASD research, gathered ideas for research priorities from many stakeholders, and convened four scientific workshops with broad stakeholder participation. Furthermore, the IACC has decided to amplify its efforts and accelerate progress by meeting four times a year (a minimum of two meetings per year are required by the CAA).

The IACC strategic planning workgroup will consider the research initiatives proposed by the scientific workshops. The IACC strategic planning workgroup will review public comment and current ASD research funding to offer recommendations for structuring the strategic plan and estimating budgetary requirements for components of the plan. The IACC will consider the recommendations of the strategic planning workgroup and define the next steps in the strategic planning process, which may include additional opportunities for stakeholder input through Web-based town hall meetings or other innovative approaches for outreach. Once ap-

proved by the IACC, a draft strategic plan will be posted on the IACC website for public comment. Upon completion, the IACC will submit the strategic plan to the Secretary of HHS.

#### CARE OF INDIVIDUALS WITH ASD LIVING IN HAWAII

*Question.* Realizing that the care of individuals with autism spectrum disorders requires an interagency approach, what suggestions do you have for those living in Hawaii faced with the unique challenges of remoteness caring for individuals with autism spectrum disorders?

*Answer.* NIH does not provide direct patient services, but several agencies that belong to the IACC address issues concerning care for individuals with ASD in remote or rural locations, and these agencies have provided information to NIH on their efforts. For example, according to the Centers for Medicare & Medicaid Services (CMS), adults with ASD enrolled in Medicaid receive many home and community-based services through Hawaii's section 1915(c) waiver for children and adults with developmental disabilities and/or mental retardation. The CMS renewed the waiver in June 2006 for 5 years. The waiver provides numerous services to about 3,000 people throughout the islands, including people with ASD, who choose to live in community, rather than institutional, settings. The operating agency for this waiver is the State's Department of Health, supervised by its Department of Human Services, the State Medicaid Agency. These two entities are charged with working together to assure that eligible individuals are aware of and can access waiver services.

The CMS also indicates that the State of Hawaii has included a "self-directed" option in the waiver that permits individuals to hire, fire, supervise, and train direct support workers. This option greatly expands the universe of potential providers, particularly in rural areas, and may include family members and spouses as providers. In February 2008, CMS approved an extension of the State's section 1115 demonstration, which will provide mandatory managed health care starting in November 2008 to aged, blind, and disabled beneficiaries in Hawaii. The expansion of the demonstration to include this group, which likely also includes individuals with ASD, will permit the State to streamline and better coordinate care and expand provider networks in remote areas.

In addition to these efforts from CMS, successful models for providing interagency services within remote and rural settings may be found among the Systems of Care Sites (including programs in Idaho, Wyoming, Alaska, Hawaii, Montana, and other States) funded by Substance Abuse and Mental Health Services Administration (SAMHSA), another member of the IACC. These programs emphasize the core principles and practices of the Systems of Care, focusing on designing services that are child-centered, family-driven, community-based, and culturally competent. Some interagency groups have used technology to employ tele-health, tele-psychiatry, clinical supervision, case consultations, and interactive videoconferencing. Training of local leaders is another important element. Some programs employ culturally-specific approaches developed with community elders that respect native traditions—e.g., oral traditions and storytelling, a holistic "heart centered" approach or understanding that the family is the central unit, rather than the individual. Cross-agency training has been used in several locations. Hawaii is conducting innovative work linking communities of practice at the local and State levels.

Furthermore, SAMHSA's Children's Mental Health Program has a grant in the Kalihi-Palama area in Oahu (urban area) that is focusing on transition-age youth with emotional or behavioral challenges. This cross-agency approach uses combined funding to surround the individual with formal and informal services and supports. The approach is appropriate in rural areas where there are often shortages of trained professional providers.

---

#### QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

##### AUTISM DEVELOPMENTAL DISABILITIES PROGRAM

*Question.* The CDC supports autism surveillance through a collaborative program, the Autism Developmental Disabilities Program (ADDP). It is my understanding that the program now has monitoring sites in 17 States. Could you comment on the CDC's plan for expanding this program and project a timeline when all States will benefit from the data collected through this program?

*Answer.* The dramatic increase in the number of children diagnosed and receiving services for autism spectrum disorders (ASD) suggests that the disorder is more common than was once believed. Understanding the prevalence of a disorder like

autism depends on collecting and analyzing data from multiple sources. In addition, it is important to use this method of data collection in multiple locations across the nation at different points in time. Doing so gives us the best understanding of ASD rates and trend in different communities in the United States.

In order to do this, CDC currently supports the Autism and Developmental Disabilities Monitoring (ADDM) Network at 11 sites (including CDC). Together with the ADDM partners, CDC provides critical data needed to answer questions about how common ASD are, whether we are identifying more children with ASD over time, and whether ASD affect certain groups more than others (i.e. boys are affected more often than girls). Also, it provides clues into potential causes that can be investigated further through research.

The goal of the ADDM Network is to provide comparable, population-based estimates of the prevalence rates of autism and related disorders in different sites over time. The program has made significant strides in attaining this goal. During the first phase of the project, as many as 16 sites (including CDC) have participated in the ADDM Network to determine the prevalence and characteristics of children with ASDs in their study areas.

In 2006, CDC awarded funds to 10 ADDM Network sites to allow the network to develop ASD prevalence estimates for 2006 and 2008. The sites are currently working on a report from 2004 and another report to look at changes in ASD prevalence across 3 time periods in 4 sites.

Establishing a national surveillance system for ASD is complex. CDC will continue to support in-depth, ongoing prevalence tracking in the current ADDM sites. Opportunities to enhance autism surveillance efforts in the United States include:

1. Developing and implementing projects that continue to link prevalence studies with screening and early identification efforts,
2. Supplementing national surveys, and
3. Conducting investigations of ASD occurrence in adults. Doing so will enhance our understanding of the population characteristics of ASDs and how they have changed over time.

#### CENTERS FOR AUTISM AND DEVELOPMENTAL DISABILITIES RESEARCH AND EPIDEMIOLOGY

*Question.* The Children's Health Act of 2000 directed the CDC to create regional centers of excellence to study autism spectrum disorders and other developmental disabilities. The Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) Network was created in response to this direction. Can you comment on the most recent research developments resulting from implementation of this network?

*Answer.* The search for the causes of autism spectrum disorders (ASD) is a top priority at CDC. CDC has engaged with partners in the Centers for Autism and Developmental Disabilities and Research Epidemiology (CADDRE) network to develop and implement public health research tools to identify potential causes.

Last year, CDC and CADDRE partners launched the Study to Explore Early Development (SEED). Through this effort, study partners expect to collect information on 2,700 children with ASD and their parents that will help answer questions about the characteristics of affected individuals as well as potential ASD causes. Researchers will explore a number of priority hypotheses such as the role of infections, genetic, reproductive and hormonal factors as well as select exposures.

As the largest epidemiologic study of its kind, SEED holds the potential to be an important complement to the array of other work occurring at the National Institutes of Health and in academia. CDC brings a unique public health perspective of studying health issues in large populations—not just among individuals or families who self-refer for intervention or study.

#### LEADING RESEARCH HYPOTHESES ON THE CAUSE OF AUTISM

*Question.* In recent years, certain vaccines have been suggested as being linked to autism. Scientific evidence and the most recent Institute of Medicine report do not support this theory. What are the other leading hypotheses among the research community of the cause of autism? How much of current autism funding is being focused on research to determine the cause of autism-related disorders?

*Answer.* Most scientists believe that there are multiple causes of autism spectrum disorders (ASD), resulting in various manifestations of the core symptoms. Twin studies provide strong evidence that ASD is highly heritable, but that the disorder involves the interaction of many genes. NIH-funded research has begun to reveal clues about how genetic variations affect the risk of developing ASDs. Although some studies have shown that mutations in individual genes are linked to only a

small percentage of autism cases, new reports suggest that part of the explanation for ASDs may be due to deletions and duplications of genetic material. Many of these are spontaneous de novo mutations not present in the parents. The study indicates that different cases of autism could be traceable to any of 100 or more genes, alone or in combination.

Environmental modifiers may also interact with genes to cause ASD or modify its expression, although such environmental mechanisms have not yet been identified. The delicate interplay between genetic susceptibility and immunological and environmental triggers may lead to differences in the healthy development of brain circuits and brain function. NIH is committed to meeting this complex challenge, determining the potential causes of ASDs.

In fiscal year 2007, the NIH spending for autism-related research totaled approximately \$127 million. About 22 percent of the funding supports grants addressing specific risk factors, including genetics, environmental mechanisms, and gene-by-environment interactions. An additional 29 percent supports grants aimed at better understanding the underlying neurobiology of the disorder, which is critical knowledge in order to identify hypotheses about additional risk factors for investigation. Several large initiatives to uncover the underlying causes of ASD involve joint initiatives and activities sponsored by the NIH Autism Coordinating Committee (NIH/ACC). The NIH/ACC functions to synchronize autism research activities funded and conducted by the various NIH Institutes (NIMH, NICHD, NINDS, NIDCD, and NIEHS).

#### SUBCOMMITTEE RECESS

Senator HARKIN. Well, thank you all again very much. It's been a very informative and constructive hearing.

The committee will stand in recess to reconvene at 9:30 a.m., Friday, April 20, in room SD-116. At that time we will hear testimony from the Honorable Richard J. Hodes, M.D., Director, National Institute on Aging.

[Whereupon, at 4:16 p.m., Tuesday, April 17, the subcommittee was recessed, to reconvene at 9:30 a.m., Friday, April 20.]